

# **GMOs in Japan**

## ***Issues, Trends and Concerns***

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# DISCLAIMER

PLEASE NOTE THAT THIS STUDY HAS BEEN COMMISSIONED FOR THE PURPOSE OF ACHIEVING AN INDUSTRY BASED IMPRESSION OF THE CURRENT CIRCUMSTANCES AND EMOTIONS SURROUNDING PRESENT AND POTENTIAL GENETICALLY MODIFIED ORGANISMS WITHIN THE JAPANESE MARKET.

THE STUDY DOES NOT INTEND TO REFLECT ANY OFFICIAL OR UNOFFICIAL POLICIES ON GENETICALLY MODIFIED ORGANISMS ON BEHALF OF THE DEPARTMENT OF AGRICULTURE AND AGRI-FOOD CANADA; ONTARIO MINISTRY OF AGRICULTURE, FOOD AND RURAL AFFAIRS; BRITISH COLUMBIA AGRICULTURE AND FOOD; BRITISH COLUMBIA TRADE AND INVESTMENT OFFICE AND MANITOBA AGRICULTURE AND FOOD.

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# CONTENTS

|                                                                                                                    |    |
|--------------------------------------------------------------------------------------------------------------------|----|
| Executive Summary .....                                                                                            | 2  |
| Preface .....                                                                                                      | 4  |
| I. Overview.....                                                                                                   | 5  |
| II. Government.....                                                                                                | 8  |
| III. Japanese Consumers.....                                                                                       | 16 |
| IV. Industries, Retail and Food Service Sectors.....                                                               | 26 |
| V. Implications for Canada.....                                                                                    | 32 |
| VI. Japanese Role in the World GM issues.....                                                                      | 37 |
| VII. Future Development of GM Products in Japan.....                                                               | 38 |
| VIII. Practical Considerations in the Development of Marketing Strategies for<br>Canadian Agri-Food Suppliers..... | 42 |
| IX. Conclusions.....                                                                                               | 44 |
| Footnotes.....                                                                                                     | 45 |
| Bibliography.....                                                                                                  | 47 |
| Appendices.....                                                                                                    | 51 |

## EXECUTIVE SUMMARY

The Japanese government had been working on GMOs since 1986. Ten years later, on August 26 of 1996, the government announced for the first time their safety assessment of 7 crops. This was the historical turning point of GMOs in Japan, however, the announcement was largely ignored by the media relegating the story to the back pages,

thereby passing unnoticed by the general public. Later, in the fall of the same year, new crops from the United States mixed with GMOs started to arrive in Japan.

Before consumers were aware of it, GMOs were already on their tables, a fact which when learned later, would trigger the start of the anti-GMO campaign in Japan. The campaign continued to grow over subsequent years, culminating in the World Action Day on May 31, 1999, when 1.7 million citizens presented a signed protest against GMOs.

Influenced by the reports from overseas, consumers' fears of GMOs grew stronger, and the campaign hit Kirin Breweries, one of the largest food and beverage companies in Japan, forcing them to declare their retreat from GMOs. Kirin Breweries' competitors were quick to follow suit. Thence, the switch to non-GMO spread like wild-fire throughout the food processing industries, responding to the demands from those in the retail sector who were looking for angles to establish their competitive edge over rivals.

The Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF), influenced by both consumers and industry, adopted the policy of mandatory labeling slated to take effect as of April 1, 2001. This was supported by the Identity Preserved handling concept and the voluntary labeling of non-segregated materials. This step actually resulted in the creation of a "gray zone" of non-segregation, in essence meaning the GMOs may be mixed with non-GMOs in processed foods. However, the food processing industry proceeded much faster than expected with the elimination of GMOs in their products. This meant that soon there were few to no food items with GMO ingredients available on store shelves in the non-segregated voluntary labeling food category, all long before the start of the labeling regulations.

GMOs in Japan were introduced too quickly, without adequately building public acceptance. The fact that GMOs offered no merit to consumers is considered another major reason accounting for their failure. Industry, as well as the government are now directing their research towards the development of new GMOs, ones that can be easily understood and more appreciated by the consumers.

Thus, the GMO's in Japan are moving into a totally new phase.

## **PREFACE**

**The purpose of this report is to summarize the state of Genetically Modified Organisms (GMO) in Japan during the summer of 2000:**

- **Where does the Japanese government stand in its administration of GMOs?**
- **What are the responses or attitudes of consumers and consumer groups?**
- **What are the reactions by the various sectors of food industries: the food processors and the distributor / retailers?**

This report was developed to present historical information and the factual current status of GMO products concerns and activities in Japan. There is no intent to promote one side of the issue over the other side. Throughout the report, opposing viewpoints will be discussed to offer the best possible balanced overview of the GMO situation in Japan.

In order to prepare this, thousand of pages of news reports and publications in both English and Japanese have been studied. Almost daily, mass media coverage of the news and topics on biotechnology, in particular that of GMO foods, is being released. It is a subject of concern for people on both sides of the argument that GMO "sells" the news. This has encouraged the use of exaggerated sensational headlines by some newspapers to catch readers' attention, thereby driving increased sales. Similar tactics by some British tabloids have been successful in scaring the public, which in turn has directly contributed to the significant consumer backlash in the UK.<sup>1</sup> Similar evidence of this was often found during the author's research, making it clear that readers of the news must always question the authenticity of the reports. The writer noticed there were an unusually high number of reports that after proper verification, turned out to be either misleading or totally mistaken. I therefore caution readers to verify as best possible the authenticity of any mass media reports they read.

Further to that, Nakamura warns in his book that newspapers and magazines have

restrictions in terms of space and TV media in terms of time allowed.<sup>2</sup> Thus, reporting on GMO often tends to be fragmented, despite the need for more complete analysis from the various sides, requiring more space or time.

## **I. OVERVIEW**

### **1. Definition of GM Products in Japan**

There exists no formal or official definition of GM products in Japan. However, several definitive explanations can be found in the various publications being distributed on genetic modification technology and genetically modified foods. Following are some examples:

“Genetically modified technology is to extract useful gene / genes from a certain plant, transferring into another plant for the purpose of crop improvement.”<sup>3</sup>

“The technology to develop a crop that has new characteristics by implanting genes of / from another crop with a certain objective. The objective may be to increase the yield or to incorporate characteristics that are resistant to disease, insects, salt or endurance to cold temperatures.”<sup>4</sup>

“Genetic engineering is to create life with new characteristics by transferring a specific gene from another life.”<sup>5</sup>

“Historically, human beings have utilized the function of plants, animals and bacteria through breeding, crossing and fermentation in order to produce better food. Genetic modification is one of the technologies developed to make better use of the functions of life. The technology extracts only the gene that is useful for a specific purpose and implants it to the life which you wish to improve, thus providing new characteristics.”<sup>6</sup>

### **2. Application / Use**

#### **a) Current Usage of GM Products**

Based on the latest safety assessment for 29 food crop plants and six food additives, a total of 38 food items became subject to the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) labeling requirements: either mandatory, exempt or voluntary

labeling. The list of these products can be found in Appendix 1.

As this legislated requirement does not come into effect until April 2001, at present there is no distinction of GMOs in the marketplace. Furthermore, processors that had previously and proactively identified GMOs on their labeling, have now backed away from this policy, due to the developed negative connotations of GMO labeled products.

## **b) Summary of GM Products Produced and Imported into Japan**

### **(i) Processed Foods**

As discussed above, processed foods are not yet subject to the label requirements. Thus, no current data exists on the actual volumes of imported products with GMO ingredients. Despite this, it is safe to assume the import of these ingredients is probably very low to almost nil, depending on the products due to rejections by the distributors and retailers in response to public demands. This is expanded upon later in the report.

### **(ii) Raw Materials**

In terms of raw materials used for further food processing, seven crop varieties are the subject of our study: soybean, rapeseed (Canola), corn, tomato, potato, cottonseed and sugar beet. As noted above, statistics on GMO vs. non-GMO imported raw materials are non-existent, as most exporting countries do not effectively segregate nor distinguish between the two.

A Japanese government publication offers some general insight by referring to the level or percentage of production of GM varieties in the exporting nations. (see Appendix 3).

A descriptive summary of this 1999 chart is as follows:

**Soybean** : Japanese domestic production was 170,000 tons, all of which was non-GM. Imports totaled 5.07 million tons, of which 76% or some 3.9 million tons came from the U.S., where the acreage of GM varieties was estimated to be 50%.

**Corn** : consumption was 16.6 million tons, of which 96% or 15.9 million tons was

imported from the U.S., where GM varieties were 33% of the total acreage.

**Potato :** fresh imports are not permitted due to phytosanitary concerns. Only processed products such as frozen, dried, fried and mashed were imported, totaling 700,000 tons. In the U.S., the GM variety acreage was only 3% in 1999.

**Rapeseed and Canola :** domestic production was 100,000 tons and 2.2 million tons were imported, with Canada supplying 1.86 million tons and Australia 310,000 tons. In 1999, Canada reported having 55% of total acreage attributed to GM Canola.

**Cottonseed :** domestic production of cotton is zero in Japan, and 172,000 tons were imported in 1999. About 20% is consumed in oil crushing and the balance used for animal feed. Japan imported 160,000 tons from Australia and only 2,000 tons from U.S., where 66% of the acreage is already GM cotton.

**Tomato and Sugar Beet :** currently there are neither imports nor domestic production of GM tomatoes and sugar beets.

### 3. GM Products Available in Retail and Foodservice

#### a) Retail

Concerns of consumer rejection are forcing retail buyers to minimize stocks of GM products to as few items as possible. Soybean Oil, Canola Oil and Soya Sauce are probably the few major products assumed to be made from GM-mixed ingredients.

#### b) Foodservice

The researcher could not find any evidence of GM products being knowingly used, again with the exception of Soybean Oil, Canola Oil and Soya Sauce.

#### c) Extent of Domestic Agricultural Production

The domestic commercial agricultural production of GM crops in Japan is nil, and what does exist is the small-scaled production in the research stations for experimental purposes.

## II. THE GOVERNMENT

The Japanese administration of GMOs is similar to that of the USA where the FDA, USDA and EPA are involved. The Japanese Ministry of Health and Welfare (MHW) is responsible for food safety, controlling such under the Food Sanitation Law, and the Ministry of Agriculture, Forestry and Fisheries (MAFF) is responsible for feed, field use and environment under the Japan Agricultural Standard Law (JAS).

### 1. Regulations

#### (a) Safety Assessment for Feed, Field Use and Environment

As early as 1986, the Ministry of Agriculture, Forestry and Fisheries (MAFF) had established guidelines for the safety assessment for domestic cultivation of rDNA crop plants and/or the import of these plants which may propagate in a natural environment, and rDNA crop plants to be used in the manufacture of feed and food products. The guidelines are essentially based on the OECD agreement on safety assessment, which encompasses the two major concepts of "familiarity" and "substantial equivalence." For overseas applicants, there are two guidelines for experimentation and six for industrial application. (See Systems and Procedures for the Application of rDNA Crop Plants, Appendix 5)

In 1995 MAFF established an Information Desk within STAFF (Society for Techno-Innovation in Agriculture, Forestry and Fisheries) in order to cope with the various inquiries from overseas and to assist with the applications for approval of rDNA organisms.

The complete list of approved items can be found in "The Current Status of Commercialization of Transgenic Crop Plants in Japan." (Appendix 6). These are the crop plants that have complied with the MAFF safety assessment guidelines.

#### (b) Safety Assessment for Food

The Ministry of Health and Welfare (MHW) in 1991 commenced assessment of food

safety basis OECD guidelines. The Subcommittee of Biotechnology under the Food Sanitation Investigation Council conducts the assessment. There are 37 members in the Council most of who are scholars, nutritionists or medical doctors.

The number of crop plants that were initially assessed started with 7 crops in August 26, 1996, and increased to 22 crops by July of 1997. Currently it now stands at 29 crop plants and six food additives.

The most recent assessment announced by the Ministry on May 1, 2000 incorporated these major changes:

- Prior to the May announcement, the safety assessment was solely on a voluntary basis, but now the Ministry has made this a mandatory requirement (Appendix 1).
- The Ministry declared that foods without a safety assessment shall be neither imported nor sold in Japan on or after April 1, 2001. The complete list of these products is also included in Appendix 1. It is important to note here that the subject for safety approval will be GM crops and not the GM products. For example, in the case of a snack food using GM corn, it will be the corn and not the snack itself that will need to be assessed. Japanese importers at the time of submitting their "Import Declarations" will then also have to submit an additional declaration affirming that GMO foods without safety assessment are not being imported. Non-compliant or falsely represented shipments will either be destroyed or shipped back, with a penalty imposed upon the importer.
- The former guidelines were abolished and the Ministry released a revised "Procedure of Application for Safety Assessment." (see Appendix 4). The new procedure requires submission of not only pertinent data on the inserted gene but now also on adjacent genes.

#### (c) Labeling

Two ministries are involved in label regulation: MAFF, under the Japan Agricultural Standard Law; and MHW under the Food Sanitation Law.

##### (i) Ministry of Agriculture

##### *The Road to Compromise*

In May of 1997, MAFF established the GMO Committee as part of the Food Labeling

Council. The members met 16 times over two years under an open session to the public. On August 4, 1999 they met to discuss the final report. The biggest contention on the agenda was that of labeling. Since opinions on labeling were split from the beginning between the consumer and food manufacturer members, no easy agreement was achieved. In the meantime, MAFF was initially reluctant to introduce the new labeling in the face of warnings from the U.S. that labeling could disrupt farm trade. The results of a poll run by MAFF itself on labeling in 1998 and the growing number of citizens participating in the non-GMO campaign influenced MAFF to move in the direction of requiring partial labeling, according to *Nikkei Shinbun* newspaper. The *Newsweek Japan Edition*, November 3, 1999 issue contained an interview with a member of parliament suggesting pressure was mounting among some members, calling for partial labeling as a point of compromise.

Eventually the compromise was made in the August 4 meeting and the Committee issued the final report on August 10.

Subsequently, an announcement was made by MAFF on November 29, 1999 calling for the new mandatory labeling under a revision of the Japan Agricultural Standard (JAS).

Highlights include:

- New law is to be in force as of April 1, 2001
- Twenty-four food items are affected by and 14 are exempted from the labeling rules (See Appendix 7 and 8)
- MAFF has decided that food products must be labeled where GM material is one of the top three ingredients, and where it accounts for five per cent or more of the total food weight
- There will be exemptions for animal feed and for food in which DNA or protein resulting from gene alteration cannot be detected using existing testing technologies [*Reuters*, Dec. 14, 1999]
- The scope of products for which labeling is required is restricted by the limited ability of scientific testing to verify GM content. For example, the analysis of modified DNA is an effective method for checking whether a product contains GM materials. But since the DNA changes with temperature and fermentation, it is impossible to verify GM levels of highly processed products, such as cooking oil and soy sauce, according to *Trends in Japan*, October 13, 1999.

In conclusion, "MAFF created a 'gray zone' or an ambiguous element in the labeling requirement in order to advance one step further in this issue," according to Nakamura.<sup>7</sup>

**(ii) The Ministry of Health and Welfare**

They have not yet reached nor announced their conclusion on labeling under the Food Sanitation Law. However, the Special Committee on Labeling under the Food Sanitation Investigation Council issued the final report on labeling on July 13, 2000, of which content is basically in line with that of MAFF. MHW has now announced their requirements for labeling. <http://www.mhlw.go.jp/english/topics/food/index.html>

For further reference, please see Appendix 11 for a summary table of labeling regulation comparisons between Japan, EU and Canada/US.

**(d) Japan Patent Office**

"The Patent Office announced in October, 1999 that they have compiled guidelines for patenting DNA fragments. The office will not patent DNA fragments whose codes are only clarified, but if these fragments are proven to be effective for specific purposes, such as diagnosing certain illnesses, it will grant patents. The office will release its new policy on the Internet and present the information in English." [Kyodo October 8, 1999]

**2. Education on GM Products**

**(a) Seminars and Lectures**

Japan Times, in its August 2, 2000 issue, reported that MAFF would sponsor public discussions on GMO through four meetings between September and November in Tokyo and Tsukuba. It goes on to say that this is the first time for the government to sponsor public "consensus-building meetings," and that Denmark started holding such meetings in the mid 1980's, which spread to other European nations in the 90's.

MAFF, however, in practice, has been holding various seminars and lectures since 1995, details of which are summarized in their report titled "Promotions of Activities to Build Public Acceptance of Biotechnology in Japan." (Appendix 9).

In its report, MAFF recognized the general public in Japan was not familiar with rDNA technology and that some seem uncomfortable with the biotechnology. Therefore, they

felt it was important to give information about biotechnology, especially rDNA technology, to the general public so that they could comfortably accept biotechnology and the products, and to promote activities to build confidence in the general public about GMO foods and its safety.

For this purpose, since 1995 MAFF has been annually running lectures for consumers, high school teachers and farmers in local cities as well as symposiums called "Biotech-forum in Living" in cooperation with universities throughout various major cities in Japan.

#### **(b) Pamphlets / Publications on GMO**

MAFF issued a pamphlet titled "Our Life and Biotechnology" in 1998 and a revised edition "Your Life and GMO" in March of 2000. The pamphlet aims to educate the public and contains chapters on GMO technology, safety assessment, distribution of GMO foods, labeling, Identity Preserved handling, scientific testing technology and the world situation on GMOs. MAFF printed 100,000 copies of these and distributed them through the Food Industry Center Foundation to over 110 organizations and more than 200 companies.

Similarly, the Innovative Technology Division of the Research Council Secretariat of MAFF has published a ninth edition of "A Quick Guide Q&A on GM crops."

### **3. Policy on GM Products**

#### **(a) MAFF Report**

The MAFF report on "Current Status of R&D in Biotechnology and its Practical Application," issued in February of 2000, carried a chapter on promotion policy in the field of biotechnology. (Appendix 10).

The report mentioned that biotechnology was key to the global solution of food, environment and energy issues, and that the technology would contribute to the improvement of productivity and quality of agriculture, fisheries and the food industry. However, it also recognized the issues confronting the application of technology such as rDNA in practice, and stressed, firstly, the need for Research and Development, and

secondly, the need to enhance public acceptance.

#### **(b) Research Organizations**

There are twenty-nine research organizations affiliated with MAFF: 19 for agriculture, one for forestry, and nine for fisheries. Private sector support for R&D is conducted through the Research Association for Mining and Manufacturing Technology, and the Society for Techno-Innovation of Agriculture, Forestry and Fisheries (called STAFF).

#### **(c) Financial Assistance**

Support programs include investments and loans through the Bio-oriented Technology Research Advancement Institution (BRAIN), the Japan Development Bank, and others. Various tax measures favouring R&D projects in the private sector are also available. Subsidizing schemes for the prefectures for the promotion of biotechnology R&D also exists.

#### **(d) On-going R&D Projects**

The MAFF policy report ("The Current Status of R&D in Biotechnology," Appendix 10) listed the following specific R&D projects to be on-going:

- Analytic research on rice genome
- Development of recombinant DNA technology for future generations
- Integrated research program for the use of biotechnological procedures for plant breeding
- Development of efficient methods for the animal genome analysis and for the utilization of important genes
- Development of highly functional materials through the structural modification of carbohydrates
- Basic research on safety assessment for practical applications of recombinant DNA organisms
- DNA bank and Gene bank

They also stated the practical applications include cell and tissue cultures, cell fusion and rDNA, and in livestock, research is being done on embryo transfer, transgenic animals and animal health.

#### **(e) Government Guidelines**

The Team Canada Market Research Centre issued a report called "The Food Biotechnology Market in Japan." It refers to the 'Basic Guidelines to Accelerate the Creation of Bio-related Industries', a plan that was approved by the Japanese government on January 29, 1999. This plan involved the five government ministries of MITI, MHW, MAFF, Education, and Science and Technology with focus on the following six areas:

- genome analysis
- commercialization
- promotion of biotech research in universities
- protection of intellectual property
- safety regulations
- public approval

#### **(f) Budget**

Under the above plan, the Japanese government has allocated Can\$3.9 billion (J¥en 290 billion) for 1999. MAFF has received Can\$220 million (J¥en 15.9 billion) of this funding. "Total government spending on biotechnology R&D in 1999 will increase by 12.3% over 1998, reaching a value of Can\$3.7 billion." <sup>8</sup>

More recently, *Reuters* reported, "in Japan the government undertakes development of new grain varieties and maintains tight control over the production and marketing of rice and other key grains. Therefore, MAFF plans to provide 1.1 billion yen (C\$15 million) to fund private research and development in the year starting April 2000.

The ministry also plans to raise its budget to 4.1 billion yen (C\$55 million) in 2000/01 from 2.7 billion (C\$36 million) the previous year to focus on rice genome analysis, the basis for development of GM crops. Currently there are no GM rice varieties in commercial production anywhere in the world." [*Reuters*, February 11, 2000]

#### **(g) Public Acceptance (PA)**

In order to enhance public acceptance, MAFF considers the following measures are necessary:

- to provide the public with appropriate information
- to make available information on the rDNA techniques, the results of R&D, and the administrative framework to ensure safety of the technology.

#### **(h) International Cooperation**

Regarding international cooperation, it was reported that “Japan plans to propose that a study group be set up to discuss GMOs under an agriculture trade negotiating group in the new round of global trade talks under WTO.

The Japanese proposal calls for the study group to look into:

- how the safety of genetically altered farm products should be assessed
- how such products should be labeled
- the impact of genetic engineering technology on human health and the environment.

GM food is expected to be the bone of contention in the trade talks. Japan and the EU are in favor of labeling, but the U.S. and Canada oppose it.” [Kyodo, Sept. 28, 1999]

#### **4. Environment**

Compared to other countries, environmental concerns stemming from GM production are relatively lower in Japan due to the absence of domestic GM food crop cultivation.

*Reuters* reported that a recent newspaper survey of 1,544 agricultural cooperatives nationwide showed 78.3% of them opposed the introduction of gene modification technology to domestic farming until the method won acceptance by consumers. [Reuters, Feb. 11, 2000]

#### ***MAFF Environment Committee Established***

With increase in the number of approved crop plants, MAFF announced in February 2000 “it will launch a committee to find ways to safeguard the environment from genetically modified crops. Ministry officials believe protecting environment is absolutely crucial in the promotion of GM technology. The committee, consisting of a dozen or so scientists and consumer advocates, will examine a variety of issues that would stem from the growing of GM soybeans and rice in Japan. Also on the agenda is the disclosure of information about genetic modification. The committee plans to issue a report by June.” [Nikkei Shinbun, Feb. 10, 2000]

### **III. JAPANESE CONSUMERS**

#### **1. The Public**

The history of GMOs in Japan began in 1986 when the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) issued guidelines for application. The Ministry of Health and Welfare (MHW) started the assessment of safety based on OECD guidelines in 1991, and five years later in February of 1996, MHW issued guidelines for food safety, followed two months later by guidelines for animal feed and feed additives.

In that same year on August 26, 1996, for the first time in Japan, the Food Sanitation Investigation Committee of MHW assessed and approved the safety of seven crops. Looking back, this was probably the turning point in the history of GMO in Japan. Nonetheless, the event passed unnoticed by the public, due to their general lack of knowledge of GMOs. As well, this was never reported as a front-page news item by the mass media.

In the fall of 1996, imports of GM soybean and corn from the U.S. began after the harvest of the new crops. In the eyes of the consumer, they were no different from what they had been accustomed to, and once they were processed into soy sauce, edible oil and corn starch, there was no way of telling the difference. In other words, "before the consumers noticed, GM foods were already on your table," according to Nakamura,<sup>9</sup> long before Public Acceptance (PA) was established.

As early as 1991, when MHW started the assessment of safety, Dr. Darryl Macer of Eubious Ethics Institute had already interviewed a number of Japanese consumers during the research for his book published in 1992 titled "Attitudes to Genetic Engineering."<sup>10</sup> Dr. Macer summarized the Japanese consumers' knowledge and awareness as:

- the public in Japan has a relatively high level of interest and awareness and believe that improved quality of life depends on scientific knowledge

- Japanese people are suspicious of safety statements made by scientists, and especially statements made by companies
- there is less concern about genetic manipulation of plants, than microorganisms, but there is substantially more concern about the genetic manipulation of animals and highest concern about that involving human cells
- there is less concern about consumption of vegetables than about the consumption of dairy products and meat

These observations continue to reflect the current-day concerns of Japanese consumers despite the fact that the book was written well before GMOs became an issue.

MAFF, in its pamphlet published earlier this year (2000), cites the following reasons account for consumer uneasiness with GMOs: <sup>11</sup>

- the eating habit is conservative by nature and entirely new products or concepts tend to be rejected
- GMO foods available in the market currently benefit the producers but not necessarily the consumers
- there exists distrust towards current scientific technology and its administration by the government body
- there exists ethical resistance for manipulation of what is considered to be natural
- most GMO comes from overseas

Major consumer polls on GMOs were conducted over the years. By the time the non-GMO movement had started in late 1996, a number of books and pamphlets were being written on the subject. The first reported poll was in August 1998, by MAFF regarding labeling. Out of 10,838 opinions received 70% were in favour of labeling. It is interesting to note, "from this point on, the Ministry began moving in the direction of requiring partial labeling," according to *Nikkei Shinbun*.

Another poll conducted by the MAFF-affiliated Finance Corporation in November, 1999 found more than 80% of respondents were reluctant to purchase and eat GMO foods. The survey was sent in the form of a questionnaire to 2,300 households nationwide, out of which 600 responded. When asked whether they would purchase

GMO foods labelled as such, 83% of respondents indicated reluctance. Asked why, 60% said they doubted the safety, while 25% replied that the term GMO was too vague for them.

The findings reinforce those reported by *Nikkei Shinbun* from a survey conducted in early October (1999) by the Tokyo Metropolitan Government. The organization polled 500 consumer monitors and received answers from 484, finding that 90% felt reluctance ranging from strong to mild. Around the same time, during November and early December of 1999, Angus Reid ran a global poll on international awareness and perceptions of GMO in eight countries. The poll interviewed a total of 5,171 adults in Australia, Brazil, Canada, France, Germany, Japan, United Kingdom and United States.

Awareness of GMO was the highest in Germany at 95% and the UK at 94%, followed by Japan at 89%. Perceived benefits were the highest in Japan at 50%, surpassing the US at 31% and Canada at 29%, whereas Germany, UK and France stood at 22, 21 and 20%, respectively. Perceived risks were also the highest in Japan at 37%. Interestingly, among the eight countries, the two risks mentioned most frequently were food safety and the uncertain impact of the foods, except in Japan where the greatest concern focused on the viruses or mutations that could be associated with GMO. The report revealed findings that knowledge of food containing GM ingredients would have a potentially negative impact on purchasing behavior.<sup>12</sup>

*Japan Times* also commented on this survey, reporting that as high as 82% of Japanese consumers feel that GMO foods are "not desirable", this constitutes the highest percentage out of eight countries. [*Japan Times*, June 24, 2000]

In summary, based on these polls, about 10 to 20 percent of consumers show no reluctance to GMO foods.

MAFF made public a summary of opinions regarding the compulsory labeling of GMO foods that will be required beginning April 2001. MAFF solicited opinions from Japan and foreign countries during November 1999. 2,065 opinions were received with the following feedback:

- The responses from consumers mostly called for expanding the list of foods and for

fixing an upper limit on the amount of “unsegregated” contents (i.e. the allowance for genetically modified ingredients)

- Feedback from food producers called for more time to prepare for the start of mandatory labeling
- Feedback originating from the US and Canada stood out, calling for a reconsideration of the plan and for its replacement with voluntary labeling on the grounds that compulsory labeling would lead to limitations on trade.

[*Nihon Kogyo Newspaper*, Feb. 27, 2000]

Various reports citing consumer rejections of GMOs can be categorized into three reasons: distrust, fear and lack of merit.

#### **a) Distrust**

Distrust of science and its administrative body in the mind of the general public can be traced to the case of the Minamata poisoning. This was a case of wastewater from a plant of Japan Chisso (Nitrogen) flowing into Minamata Bay over several years, causing organic mercury poisoning. People who ate fish or shellfish suffered from poisoning, and the number of victims officially recognized as patients numbered 12,615. Victims sued the company and the government, and the final settlement took over forty years from the outbreak of the disease. In the process, Nakamura reports in his book “some scientists presented false findings in trying to defend the existence of the plant for the sake of its contribution to the local economy.”<sup>13</sup>

Like Europeans who have been sensitized to food-safety issues with the outbreak of “mad-cow” disease, “Japanese consumers have been particularly unwilling to accept government assurances that the products are safe. In Japan, the credibility of the Ministry of Health and Welfare was severely damaged in 1996 by the outbreak of E. coli as well as by the revelation that its bureaucrats had knowingly allowed the sale of HIV-tainted blood products. This was a scandal that broke the same year that the ministry approved the first of 22 GMO crops for human consumption.”<sup>14</sup>

It was also in 1996 that the Consumers Union of Japan (CUJ) started their non-GMO campaign.

The following case stories of beef furthered consumers' distrust of the government and exemplified the lack of communication between two levels.

**(i) What's the Beef?**

"When the beef from 144 cloned cows born at Japan's public and private research institutes was put on the market without informing the public in April 1999, it caused a great deal of commotion, much of which involved the issue of labeling.

In September 1999, designated butchers and barbeque restaurants began advertised trial sales of beef from cows cloned by embryo-transfer. Customer reaction has been broadly positive and the beef sold out fast but the responses were mixed." [*Trends in Japan*, November 15, 1999]

**(ii) Beef over Clone Cows**

"When *Nikkei Shinbun* reported in April 1999 that cloned cows bred in research stations had been shipped to market in Nara, MAFF said the meat had been sold for four years throughout parts of Japan. The Japanese Consumers Co-operative Union (JCCU) demanded that the ministry has the responsibility to explain why these products are safe. The consumers then would be able to choose to accept or not. The problem is that everything is over by the time consumers find out about the consequences." <sup>15</sup>

MAFF officials played down these concerns, arguing that the process involved splitting fertilized eggs rather than altering genes, and that the technology was different from the nuclear transfer method used to clone Dolly in UK. MAFF's Livestock Industry officials commented, "There is no genetic engineering involved in this process. It is the same thing as having twins and triplets under natural circumstances, so I don't know why it has become such a big deal." [*Reuters*, April 14, 1999]

**b) Fear**

Consumers' fears about GMOs initially arose, from overseas media reports. These include the Triptophane accident, birth of Dolly, Nature magazine's Super Weed report, Dr. Pusztai incident, the prohibition of growth hormones by EU, (which Japan had

approved) and another Nature report on the Monarch Butterfly.

Secondly, the non-GMO activity groups and scientists raised a series of questions regarding the safety of GMO foods, most of which were left unanswered in the minds of consumers. Those were questions related to toxicity, allergies, impact on life and ecology over a long-term basis (decades), and the fear of creating super new and unknown life.

### c) Merit to Consumers

Perceived merits of GMO foods to consumers are not visible since the foods are not different in shape, nor more nutritional, nor any cheaper than the conventional foods. Any merit that was attributed to GMO products was concerned with the benefit of producers. The issue of ecological merit was never effectively promoted.

The general public's concern gradually led to the rise of various movements beginning around the end of 1996.

## 2. Consumer Groups

### a) Consumers Union of Japan

#### Education and Action: the Non-GMO Campaign

Soon after the start of the import of GMO corn and soybean in the fall of 1996, the Consumer Union of Japan (CUJ) embarked upon a Non-GMO Campaign.

CUJ is a consumer organization with around 6,000 individual members, plus over 2,000 corporate members including consumer cooperatives and commercial companies. Setsuko Yasuda in the secretariat office was in charge of the campaign for CUJ, but as the campaign grew, she resigned from CUJ to work full-time leading the Non-GMO campaign.

Initial objectives of the Campaign, which still hold even today, are two-fold: firstly, not to buy, eat nor allow marketing of GMO foods; and secondly, to call for the labeling of GMO foods. Environmental groups and 500 local assemblies, ranging from consumers to farmers to religious bodies, soon joined the campaign.

Ms. Yasuda, secretary-general of the campaign, commented that "the Japanese government's safety checks are based on the concept that GM crops are substantially equivalent to conventional ones unless they differ significantly in terms of composition and nutrition, an idea endorsed by biotechnology companies developing GM seeds."

"It is misleading to say a crop in which a gene from a bacterium or different species that is inserted is "substantially equivalent" to a conventional crop, and the group cannot trust the government's safety checks based on this assumption."

As part of the campaign, Ms. Yasuda presented one million signatures to the Health and Welfare Ministry in 1997, and 1.7 million signatures in May 1999, asking that the imports of genetically engineered food products be halted until the health risks could be evaluated. She wanted new safety guidelines for the approval of GMOs, and until then, stop the introduction of new varieties.

Ms. Yasuda (CUJ) also led a boycott campaign against Kirin Breweries products, an unprecedented move in Japan's usually docile consumer market, when Kirin paid an American company to obtain technology to develop genetically recombined tomatoes for longer storage life. Kirin decided to delay introduction to the market, saying consumers are "not ready."<sup>16</sup>

The campaign announced complaints on July 29, 1999 that unapproved GMOs had slipped past the government's safety checks and had found their way into corn snacks. The campaign had collected five corn snacks and one cornstarch product produced by three different manufacturers, and requested Genetic ID in Iowa to analyze. The reasons for selecting Genetic ID was because of the company's superior capability to analyze 0.01% of GMO content and their possession of "primers" of the particular corn varieties, the campaign claimed.

The Ministry of Health, in March of 2000, made a press release concluding that they could not find evidence of unapproved GM corn contained in the snacks mentioned, according to their method of testing. MHW elaborated on their method of testing and findings in their website. There was a case reported out of Washington on September 18, 2000 that both FDA and EPA had started investigations into taco shells from Taco

Bell for possibly containing StarLink corn, a GM variety developed for feed purpose.

The above was countered by an article of September 22, 2000 by Steven Milloy of [www.Juncscience.com](http://www.Juncscience.com), suggesting doubt about the credibility of the group that originated the complaint, and Genetic ID who tested the Taco Bell shells. [*Nikkei Shinbun*, September 19, 2000 and AGNET September 23, 2000] In the eyes of the consumer, these two cases are confusing, simply leaving the impression that there is no way of telling whom to trust.

#### (i) My Tofu Project

"My Tofu" was part of the rapidly spreading "soybean field trust" system launched by the Consumer Union of Japan in 1998. Under the trust system, a consumer becomes the "owner" of about 30 square meters of soybean field for 4,000 Yen per year. The organic crops harvested would be handed to the consumer in the form of products such as tofu, miso and soy sauce. The project started with about 15 groups, each gathering about 100 consumer participants. The number of the groups expanded to over 60 nationwide in 1999. "To those who don't feel comfortable with tofu made from imported soybeans, many of which are genetically altered – why not join us?" an inviting campaign leaflet asks.

As stated previously, the Consumer Union of Japan launched their anti GMO foods campaign in 1996 when the government approved imports of GM soybeans, rapeseed and corn. Public participation in the anti-GMO movement, however, really escalated in 1999 when debates intensified on whether or not to introduce a mandatory labeling system, letting the consumers know and giving them a choice in their purchases.

On May 31, 1999, a record 1,700,000 citizens presented a comprehensive list of demands to the government. The day marked the beginning of global weeklong days of action against GMOs involving lectures, press conferences and TV interviews in Tokyo, Chiba and Fukuoka. The petition was presented simultaneously to the Ministry of Agriculture and Ministry of Health and Welfare by a coalition of citizen organizations headed by the Consumer Union of Japan.

Demands included:

- immediate compulsory labeling of all GE foods
- a moratorium on domestic production of GE crops
- a suspension of research on the application of GE to rice and cloned cattle
- a recall of cloned beef, and measures to ban its marketing
- promotion of organic farming.<sup>17</sup>

The Consumer Union of Japan (CUJ), led by Yoko Tomiyama, sent a letter dated October 6, 1999, to American farmers and agro-related companies, citing scientific data that supported potential health and environmental hazards of GMOs, urging farmers to segregate GM and non-GM products exported to Japan.<sup>18</sup>

In the original letter, JUC goes on to state that such IP (Identity Preservation) handling would lead to help establish Japanese consumer confidence and trust towards US crops and food products.

#### b) Japanese Consumers' Cooperative Union (JCCU)

A large portion of Japanese food production and distribution is through the co-ops, which are consumer membership organizations. The Japanese Consumers' Cooperative Union (JCCU) is an association of 646 membership co-ops, representing 20 million individual members, or one out of every six Japanese.

#### (i) Education

As early as September 1997, JCCU published a guideline paper for their membership coops, explaining the GMOs. The paper stressed that information on the subject was lacking, there was no public acceptance established, and that there was no reason either to object or to support the GMOs. The role of the consumer cooperative was to inform their members and guarantee the right for them to choose. It also recommended to keep informing the members on the subject through study groups and coop publications.

JCCU ran a series of seminars and distributed pamphlets on GMOs among its members, along with a Q&A booklet to its officers. They also established guidelines for voluntary labeling in January of 1998.

## **(ii) Actions**

JCCU, through its local members, was active in having local municipalities adopt proclamations requesting MAFF and MHW to establish mandatory labeling of GM foods. They succeeded in encouraging 1,250 municipalities, representing 40% of all of Japan, to submit this request to the government.

As part of its labeling program, JCCU invested 8 million yen in equipment to test for genetically engineered ingredients in foods. They would initially test soy ingredients, and plan later to test final products, as well as corn and potato products.<sup>19</sup>

On November 1999, JCCU issued a statement for the occasion of the OECD NGO Consultation on Biotechnology and Food Safety, in which they demanded the following:

- to have a guarantee on the consumers' right-to-know and to choose through mandatory labeling
- to create an international segregated distribution system without any increased cost to consumers
- to establish an international standard for ensuring trace-ability
- to establish active participation of consumers in the process of "Risk Analysis" and "Risk Management"
- to disclose to consumers information that governments and companies possess, particularly information concerning food safety and environmental impact.

They also asked for the guarantee of a long-term monitoring study on human health and the ecological system, citing an article in "*Nature*" magazine, reporting the death of the butterfly caterpillars after intaking the pollen of GM crops.<sup>20</sup>

Following the MAFF labeling requirement announcement on November 11, 1999, JCCU submitted a statement to the Minister, praising the adoption of the mandatory labeling, while requesting an expansion of the number of products to be labeled and to have more severe checking and research capacities.<sup>21</sup>

c) **The Japan Descendants Fund** is a nonprofit group that has succeeded in provoking widespread concern among Japanese consumers about chemical emitting plastics in food packaging and the use of post harvest chemicals on food. Junichi Kowaka is a food safety activist with the Fund and he has made a video "The Dangers of Recombinant-DNA Food." More than 1,000 copies have been sold for Can\$200 each and are often shown at lectures and gatherings by consumer, environmental and religious groups.

A potato bug is shown munching on the deep green leaf of a potato plant that has been genetically engineered in the U.S., the narrator says, to produce a toxin that kills Colorado potato bug larvae. The bug then falls off the leaf, flailing its legs in the air in a state of agony.<sup>22</sup>

#### **d) Municipality School Lunches**

The City of Kawagoe is a suburban "commuter town" near Tokyo where the officials declared that nothing on their school lunch plates can contain GM foods. The Education Committee of Kawagoe City provides meals for 28,000 students in 56 local schools. Kawagoe was to be joined by other eight Japanese local governments that have also decided to eliminate GM foods from their school lunch program.<sup>23</sup>

Finally, the Japanese consumers' response is well described in the *Canadian Chamber of Commerce in Japan* magazine when it featured an article of GMO foods:

"A growing number of consumer and environmental groups, and even some scientists, ask at what cost these benefits come from. ... that the long-term health and environmental effects of growing genetically modified foods are, at best, unclear and possibly even detrimental. They are therefore asking, at a minimum, to be given the freedom to choose whether or not to consume such products through informed labeling."

## **IV. INDUSTRIES, RETAIL AND FOOD SERVICE**

Following the August 10, 1999 submission of the final report by the MAFF Labeling Committee, the role of protagonist in the GMO drama shifted to the industry and retail sectors.

### **1. Food Processors**

One can see in the chronology of events (Appendix 12) that no important topics related to the industry sector arise until August 1999, when Kirin Brewery made an announcement on August 24 that "it is freezing its effort to develop longer-lasting tomatoes using Genetical Engineering. Kirin is bowing to consumer fears about foods using genetic technology. It promised not to continue R&D on tomatoes for the time being and to substitute unaltered corn for the genetically-enhanced corn it has been using as a beer ingredient." [*Comline News Service* 24/08/99]

The above was one of the earliest announcements made by a food manufacturer, declaring they would not use GM ingredients. This was followed only two days later by a competitor of Kirin, Sapporo Breweries, Japan's third largest beer maker, stating, "it will stop using GM corn to make beer. Although beer is exempt from the government's requirement on labeling which takes effect on April 1 2001, Kirin and Sapporo plan to switch to non-GMO corn saying they cannot ignore such food safety. Both plan to leave prices unchanged." [*Reuters* 26/08/99]

As mentioned in the *Reuters* report, while neither DNA nor protein is considered to be evident in beer, the breweries took precautionary measures to avoid anticipated consumer concerns. Asahi Breweries then joined the move with the announcement that "they plan to phase out the use of GM corn in its beer production by April 2000. They import about 130,000 tons of corn, mostly from the U.S." [*Kyodo* 24/09/99]

Henceforth is a summary of food manufacturers which have appeared in the media, announcing their switch to non-GM ingredients or materials. (see Appendix 13 for expanded details).

### **Manufacturers Using Corn**

|              |        |                    |
|--------------|--------|--------------------|
| Kirin        | beer   | August 24, 1999    |
| Sapporo      | beer   | August 26, 1999    |
| Asahi        | beer   | September 24, 1999 |
| Tohato       | snacks | August 31, 1999    |
| Nippon Flour | flour  | December 20, 1999  |
| Bourbon      | snacks | June 12, 2000      |

#### **Manufacturers Using Soybean**

|                        |             |                    |
|------------------------|-------------|--------------------|
| Fuji Oil               | oil crusher | August 31, 1999    |
| Nisshin Food Products  | noodle      | September 10, 1999 |
| Ajinomoto              |             | December, 1999     |
| Kibun                  | soymilk     | December 21, 1999  |
| Tofu Association       | bean curd   | August, 1999       |
| Kurehara Food Products | miso paste  |                    |

In late 1999, a TV commercial run by a "Natto" (fermented beans) manufacturer showed a pigeon choosing and preferring non-GMO over GMO soybean. An aggressive move such as this by a competing company in the industry made the processors using GMO uneasy, clearly placing them in an awkward position.<sup>24</sup>

*Nikkei Shinbun* newspaper, on November 8, 1999, ran a survey among 323 major food producers that showed that 14% had already switched to non-GMO products, and 66.9% said they planned to switch in the near future or were considering switching. Eighty per cent of the companies using GMO products or those who were unsure if they used GMO products were considering shifting to non-GMO. Of the companies planning to switch, 44.9% were doing so because of pressure from retailers. More than 80% expected costs to increase by 20% or more, and 32.3% planned to pass these costs onto consumers.

145 firms of the 323 surveyed have decided to stop using GMO products well ahead of the labeling deadline.

## **2. Importers**

Japanese importers or the trading houses have traditionally played a major role in securing / importing the food ingredients for the processors from overseas. As result of the processors' en masse movement to switch to more traditional, non-GMO ingredients, importers were scrambling to establish systems of segregated distribution for non-GMO crops in response to rising demand from domestic food manufacturers. The move was concentrated mostly in soybeans for edible purposes since the related industries became aware through the open session discussions of the Labeling Committee that, firstly, soybean products with the exception of soya sauce, were going to be designated as foods requiring labeling. Secondly, the Identity Preserved (IP) handling system was the recommended tool for segregation of GMO and non-GMO ingredients. Normally, Japan imports five million tons of soybeans, with approximately 70% coming from the United States. "Japanese requirements of edible purposes soybeans are about one million tons in total, of which half is consumed for Tofu and its products." (Appendix 14) In response, importers moved quickly to secure traditional or non-GMO soybeans through some type of IP handling system.

ITOCHU Corporation announced in October 1999 their switch to non-GMO supplies for all of its import of soybeans for human consumption. For this purpose, it has been setting up a distribution system within the U.S. to store and ship unmodified soybeans exclusively.

HONDA Motor Co., said in October 1999 that it would build a plant in the United States and hire farmers to supply only conventional soybeans. Honda had been importing grains for years in return for their export of automobiles, in order to appeal their efforts to offset the balance of trade.<sup>25</sup>

MITSUBISHI Corporation also moved to set up a system of segregated distribution, building separate storage facilities both at export and domestic points.

By the middle of 2000, the majority of the importers in Japan had established systems and sources of importing non-GMO soybeans, as well as other ingredients such as corn grits, corn sweeteners, etc.

In soybean, the move led to the opening in May 2000, of the non-GMO futures market for the first time in the world, in the Tokyo Grain Exchange, as well as two other local exchanges.

To summarize, the establishment of the "non-segregated" category on labeling, basis the IP handling concept supported MAFF's decision for mandatory labeling. Both consumers and the industry welcomed the move as a positive step forward, although they considered the non-segregation to be a "gray zone." Consensus in the food industry as well as the expectation by the Ministry of Agriculture was that there would be a number of products labeled "non-segregated." Quite unexpectedly, however, the Beer, Tofu, Natto and Snack industries all moved to eliminate GMO ingredients.

The state of the industry is well summarized in the following reports:

"By the time April 1, 2001 comes around, there will be no products that labeled "non-segregated." <sup>26</sup> "Japanese companies are moving to eliminate GMOs from their products long before the labeling rules take effect." [*Japan Digest*, August 24, 1999]

### **3. Retailers**

#### **(a) JUSCO Starts Labeling**

Four nines are the symbol of the purity to imply 99.99% purity in Japan.

JUSCO, the third largest supermarket operator in Japan, announced on September 9, 1999 that they would start voluntary labeling of all 30 food items included in the JAS revision on GM foods labeling. While initially the labeling would be done on their own Private Brand called "Top Values," Jusco intended to request all National Brand manufacturers for cooperation on labeling, targeting to complete all product labeling by October 1, 1999.

Jusco's labeling was done to segregate products into three categories:

- No GM ingredients or foods used
- No GMO 'major ingredients', but GMOs may be found in other ingredients or additives
- May contain GM raw materials.

Furthermore, Jusco announced on October 7, 1999, that they would include the labeling of products such as soya sauce, corn flakes and salad oil, which were left to voluntary labeling in the government regulations. The move would boost the number of food items labeled to 63 from the initial 34, and Jusco estimated the final number of food items would ultimately reach 200 to 300 items. [Jusco news release October 7, 1999]

*Netlink Health Japan* reported on October 14, 1999, that "a telling illustration of this important change is the setting up of separate sections at supermarkets, despite not being required by government, that segregates soy products made with imported GM beans and those that claim to use only the local variety."

#### **(b) *The Other Supermarkets***

Unlike the food processors that followed competitors' switch to non-GMOs, there were no reports in the news media of other super markets following Jusco's lead. I therefore conducted my own investigative research, visiting and interviewing management at Itoh-Yokado, Daiei, Seiyu, Olympic and Meidi-ya stores on several occasions during August and September of 2000.

My findings were:

- None of the above-mentioned stores had declared the adoption of non-GMO labels as Jusco had done.
- None of the stores visited had established separate store sections as Jusco had implemented.
- One could not find any products on the shelves that positively stated GMOs were being used.
- The only GMO-referenced labeling one could find was that saying, "no GMOs are being used as ingredients" among only a handful of products (e.g. one leading national brand of soya sauce, and several Natto and Tofu products).
- As a consumer, one is left to only assume those designated products that do not carry "non-GMO" labeling are ones which may contain GMO ingredients.

During interviews with the management-level people of the supermarkets, it was clear

that their policy of approach to GMOs was more passive than that compared to Jusco. They had store employees ready with answers to satisfy consumers when asked, but they had no plans to introduce separations of section in the stores. Overall, they were not as anxious as Jusco was to the voluntary labeling, and the reasons cited were because they were not confident they could adequately fulfill their "responsibility to supply" in terms of volumes, should they switch all of the designated products to non-GMO products.

## **V. IMPLICATIONS FOR CANADA**

### **1. Canadian Agri-food Trade with Japan**

#### **a) Commodities**

##### **(i) Wheat**

There are no GMO wheat varieties registered for production nor grown commercially in Canada. A few seed companies have been working on different GM wheat products which could arrive in 2003," according to the web-site, [www.cropchoice.com](http://www.cropchoice.com), June 30, 1999.

Nakamura in his book, reporting on his August 1999 visit to Life Science Institute of Monsanto, stated certain varieties of Canadian wheat were being developed to provide disease resistance and that Monsanto estimated these varieties could be made available in 2002.<sup>27</sup>

Tom Crosbie, Monsanto's global head of plant breeding, was quoted in *Farmers Weekly*, February 25, 2000: "Gene transformation is just one particular wrench in the biotechnology tool box. We have lots of other tools to accelerate the development of new wheat varieties... Biotech methods such as gene mapping and molecular markers will transform conventional breeding... But GM techniques could still have a role.

But "even at this early point, there are some overseas customers who have already informed the wheat industry that they only want to purchase traditional wheat," says US Wheat, which is a farmer-funded organization that develops international markets for American farmers. US Wheat is not opposed to biotechnology but the group agrees that customers / market come first, and they should have the right to choose between

GMO and non-GMO. [[www.cropchoice.com](http://www.cropchoice.com), June 30, 1999]

The situation is similar in Japan.

The US Wheat Associates' Tokyo Office warned that importing GM wheat would be a "highly sensational and emotional issue" in Japan and could "lead to a total boycott of US ag-products." [*Manitoba Co-operator*, March 23, 2000]

According to the reports from the Canadian Wheat Board (CWB), the Japanese Food Agency, the government's buying agency for wheat and barley, the Japanese Millers Association, and Bakers Association all expressed a demand for non-GMO wheat during a CWB mission in December 1999.

Although no GM grains have ever been commercially approved in Canada, Dr. Nagao, a leading figure in the Japanese milling industry, formerly with Nisshin Flour Mill and currently a director of the Wheat Flour Institute, indicated during a mission to Japan in March 1999, that vendors would have to fear losing market shares if GM wheat happened to be mixed with regular wheat export to Japan.

Interestingly enough, the Japanese debate on labeling included a discussion on wheat and rice declaring that since there are no varieties of GMO either approved or commercially produced in Japan, it is not desirable to allow labeling to say non-GMO being used. The Committee feared those wordings may be used for window-dressing individual products.

## **(ii) Canola**

### ***Why Japanese Crushers are Not Switching to Non-GMO Oil?***

Dale Adolphe of the Canola Council of Canada said, "the world market of Canola is segregated on a geographical basis" during an overview of GMO. If an international buyer wants non-GMO canola, all they need to do is source through Australia and Europe."

Japan required 2.2 million tons of canola in 1999, of which 85% came from Canada and 14% from Australia. Considering the labeling requirement and an almost frantic switch

to non-GMO ingredients among food processors, it was expected that Japanese crushers might rely more on the Australian supply in 2000. This turned out not to be the case for the following two reasons:

Firstly, major crushers concluded that they could not afford to make two different oils: GMO and non-GMO available to consumers. Had the market been prepared to pay for the extra cost incurred by crushers to have separate bins and tanks, plus the cost of cleaning crushing lines, crushers may have marketed, albeit unwillingly, two types of products. However, consumers were not prepared to pay the extra price. This is now more true with a slowing Japanese economy and with individual consumption rates remaining low.

Secondly, the majority of the crushers have limited options because they are not prepared to fulfill their supply obligation wholly in non-GMO seed. Quite simply, there is not enough non-GMO seed in the world available at a competitive price. Since there is no requirement for labeling of Canola oil, Japanese crushers can continue to count on Canada for the bulk of their supply needs. Furthermore, the crushers have no intention of voluntary labeling GMO Canola as an ingredient since this could be considered a counterproductive strategy.

### **Problems for Canola in the Future**

#### **1. Future of Labeling**

Although Canola oil is exempted from mandatory labeling for now, there exists a fear amongst people in the crushing industry that, should technology advance so that oil from GMO seed can be identified separately from non-GMO oil, they may be compelled to labeling in the future.

#### **2. The Switch to Non-GMO oil**

As seen in the consumer sector, a certain number of municipalities ordered a switch in their school lunch program to non-GMO oil, which was mostly the domestic rice bran oil, albeit higher in price. The leading rice bran oil crusher, who was unable to supply the required volume due to the small content of oil extracted from rice bran, soon moved to import Australian unrefined oil to be processed in his plant.

This type of demand created by the switch to non-GMO ingredient oil is so far limited due to a higher price, however, distributors and retailers are approaching crushers seeking increased supply of non-GMO ingredient oil at reasonable prices. In doing so, both distributors and retailers are hoping to establish a competitive edge in the market. Recent reports show there are a number of inquiries seeking non-GMO unrefined oil, and it may not be long before we see the expansion in the non-GMO oil.

### **(iii) Edible Soybean**

Out of a total demand of roughly 5 million tons for soybeans in Japan, 4 million tons are for crushing purpose and 1 million tons are for edible purposes. About half of the latter is consumed in Tofu and its products, 160,000 tons in Miso paste, 130,000 tons in Natto and the balance in other minor products. Statistics are attached in Appendix 14.

Most shipments from Canada arrive in containers and whether they consist of white hilum or other varieties of beans the shipments must rigidly follow the identity preserved (IP) handling guidelines as set up in MAFF manual. Shippers in Canada are generally well aware of the procedure and documents required since this information is requested by the buying importers. It is important to note that an unintentional mixing level of 5% is allowed, however, the tolerance becomes nil when mixed with varieties that are not approved in Japan.

### ***Izumi Foods***

Izumi Foods is a medium sized Tofu manufacturer in Tokyo. Among an estimated number of 3,000 Tofu manufacturers in all of Japan, Izumi ranks anywhere between 50th to 80th in size. In addition, there are about 13,000 corner Tofu stores, mostly run by family operations that produce fresh Tofu daily. The marketing competition in the industry is severe.

Mr. Aoyama, president of Izumi, buys soybean mostly from Canada. He switched to non-GMO certified soybean about two years ago. On a voluntary basis, he took 1,000 kernels of soybean received on June 30<sup>th</sup>, 1999 and had them sprouted in their own laboratory, then sprayed the kernels with Round Up Ready. 998 beanstalks died but

two remained fresh and green in colour. His conclusion was that there were two kernels of GMO soybean among 1,000.

Izumi had received certificates from the distributor and shipper that the soybean he purchased were GMO-free. The Japanese government allows up to a maximum of 5% contamination for an IP handled ingredient. He is therefore well within the government approved level that would allow the company to call their product GMO free.

The problem the company faces, however, is that his Tofu would be classified as GMO positive by an analysis lab, since the current analytical technology is available only for qualitative analysis and not quantitative for Tofu, although the quantitative analysis is available in the ingredient level. Mr. Izumi requested the distributor to make sure the unloading pipes are cleaned before handling his soybean, but was told it is almost impossible to ensure a complete cleaning. For this reason the company was unable to call their Tofu completely free from GMO.<sup>28</sup>

### **(iv) Value-Added Processed Foods**

Furthermore, even after April 1 of 2001, no processed foods need be labeled as such unless one of the top three ingredients are GMO, and unless its ingredient comprises more than 5% of the total weight.

In commercial practice, however, there exists a "witch-hunting", for lack of a better word, of GMOs amongst Japanese retailers. Once a concern is voiced by consumers, retailers will send a product for analysis with its charges automatically passed onto the importers. Current analysis detects qualitative "yeah or nay" levels and since no quantitative results can be obtained, one is branded as containing GMOs even if only a trace exists, and the product will be rejected.

When corn snacks using corn grits came under close scrutiny, importers of maple sugar cookies were even asked whether corn grits had been used as ingredients, and if not, to submit proof of such non-use in writing. Currently, as the Japanese market remains overly apprehensive, it is recommended to be aware of the sensitivities associated with the use of GMO ingredients. [AUTHOR'S OWN CONCLUSION]

## VI. JAPANESE ROLE IN THE WORLD GM ISSUES

### (i) World Trade Organization

*Kyodo New Press* reported on September 28, 1999 that Japan was to propose a GMO study group at the WTO talks:

"Japan plans to propose that a study group be set up to discuss genetically modified organisms (GMOs) under an agriculture trade negotiating group in the new round of global trade talks set to begin late this year under the World Trade Organization (WTO), government sources said Tuesday.

The Japanese proposal calls for the study group to look into how the safety of genetically altered farm products should be assessed, and how such products should be labeled, in different countries, and to scrutinize the ongoing debate on GMO agricultural products at international organizations, according to a copy of a draft of the proposal obtained by *Kyodo News*. It stresses the need for appropriate ways to assess the potential of genetic engineering and the impact of such technology on human health and the environment, underlining the importance of answering consumers' concerns about genetically altered farm products.

Tokyo will detail the proposal at a two-day meeting of agriculture ministers from Japan, Australia, Canada, the European Union and the United States opening in Canada and then present it to the WTO secretariat, the sources said. The latest proposal follows one presented by Japan to the WTO in June 2000, in which Tokyo appealed for creating a forum to deal with genetically altered food on a multilateral basis.

Genetically altered food is expected to be a "bone of contention" in the trade talks, pitting Japan and the EU against the U.S. and Canada over whether such food should be specially labeled. Japan and the EU are in favor of special labeling but the U.S., the world's biggest producer of genetically altered food, oppose it.

In line with a proposal by a government advisory panel, Japan's Ministry of

Agriculture, Forestry and Fisheries plans to require some foods made from genetically altered crops to be labeled starting in April 2001."

### (ii) Codex Alimentarius Commission (CODEX)

FAO and WHO jointly established Codex in 1962. In its general meeting held in Rome in June 1999, Japan proposed to establish an Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. This was agreed upon unanimously, and in March 2000 the first meeting of the Task Force was held in Chiba, Japan. The second meeting is scheduled to take place again in Japan in March of 2001, with a final objective of submitting a report to the general meeting of Codex before 2003.

#### a) Influences of Overseas GM Campaign on Japan

Setsuko Yasuda, spokesperson for the Consumer Union of Japan, used the word "guinea pigs" when she was quoted in "GMF Market Intelligence" April 17, 1998, published by Genetic Id, L.C. claiming, "Japanese are being used as guinea pigs by rich countries and their corporations in the experiment of expanding genetically modified foods."

By coincidence, Dr. Pusztai of the U.K. used similar words later, as reported in the *Globe and Mail*, February 20, 1999, saying that he would not eat GM food himself and that it was "very, very unfair to use fellow citizens as guinea pigs." Regardless whether this was a coincidence, there is no doubt that in this day and age where information is so accessible via the Internet, overseas campaigns on GM foods influence Japan almost instantaneously.

A comprehensive list of demands was presented to the Japanese Minister of Agriculture with 1.7 million signatures of citizens on World Action Day for GM foods, May 31 1999. On the same day, a UK scientist, Dr. Mae-Wan Ho was invited to Japan for a lecture to the Consumer Association of Japan, which was the organizer of this action day. It is my understanding that activist organizations in Japan are not only exchanging information but also coordinating their actions with the similar group overseas.

## VII. FUTURE DEVELOPMENT OF GM PRODUCTS IN JAPAN

### 1. Trend of Acceptance of GMO Products

"There is a wide gap in knowledge between scientists and the ordinary public," said Yutaka Tabei, deputy director at the Farm Ministry's Innovative Technology Division. He continued saying, "if people understand enough about the technologies, they will understand the safety of GM crops," adding that the technologies are necessary for Japan as it is the single biggest food importing country in the world. [[www.netlink.de/gen/Zeitung/1999/991231a.htm](http://www.netlink.de/gen/Zeitung/1999/991231a.htm)]

In light of this reality, Japan may feel the need to reassess its approach if there is to be any successful future introduction of GMO products in Japan.

It is felt this can be best be achieved by working with Japan's main staple: rice. Creating a new functionality of rice using GM technologies, such as incorporating genes to reduce cholesterol levels, to prevent pollen allergies, and to reduce high blood pressure and diabetes.

Rather than providing merits to the producers, a different tack of promoting the merits available to consumers would go much further in terms of gaining PA (Public Acceptance).

Rice, being the most important food product in Japan, is the easiest and the quickest commodity to offer the merits of GM technology to Japanese consumers.

The manner and order of the development of GMOs in Japan should have been reversed from the beginning. The development of corn varieties resistant to insects could have and should have come later, once a sound PA was established amongst consumers.

[Nakamura, *Sensor Focus*, *Jetro Sensor Magazine*, September, 2000]

## **2. Development of GMO Products in Japan**

### **a) Rice**

Japan's ag-biotech research and development is proceeding rapidly with GMO rice. The International Rice Genome Sequence Working Group held meetings at Tsukuba, Ibaraki Prefecture in March 2000. Researchers from Japan, China, the U.S., South Korea and the EU agreed on research plans and assigned chromosomes to be analyzed to each group. Any country that has the capacity to analyze a certain number of base pairs per year is invited to join in the research. Japan has taken the lead in the analysis of the rice genome, having mapped the largest number of base pairs. "Ag-Biotech research goes on," affirms GMF Market Intelligence [[www.vibrantplanet.com](http://www.vibrantplanet.com)].

Manufacturers are increasingly switching the focus of their research and development strategy from benefiting producers to benefiting consumers, by producing tastier, healthier foods. Japan Tobacco Inc. has now developed rice that contains less glutelin, a protein that causes the rice to lose its taste. At the MAFF research centre, rice with improved health benefits is being developed. It has been genetically altered to give it the power to reduce blood cholesterol levels.

### **b) Trees and Feed**

Toyota Motor Corp. will branch out into the biotechnology business, focusing on reforestation and production of domestic animal feeds, company officials announced earlier this year. The nation's top automaker plans to begin planting overseas genetically engineered trees by the middle of the year and to produce feed in three to four years, the officials said. Toyota has been doing biotech research since 1990, and has succeeded in developing new varieties of fast-growing trees and agricultural products. The company plans to launch reforestation projects in desert areas sterilized by slash-and-burn farming techniques, the officials stated, adding Toyota plans to apply its technology to also planting roadside trees in the future. As for feed for domestic animals, they said Toyota is considering producing fast-growing sweet potatoes through genetic engineering.

[[www.netlink.de/gen/Zeitiung/1998/980213b.htm](http://www.netlink.de/gen/Zeitiung/1998/980213b.htm)]

### **c) Beef**

The incidence of cattle cloning will continue to increase at a high rate due to the demands for very high-quality beef in Japan. Success in this area could be welcomed by the public, as a reliable source of high quality beef available at a lower cost. However, work such as this is likely to find a market only in Japan, where beef roasts of the finest quality sell for well over \$150 a pound.

[*The Food Biotechnology Market in Japan*, The Team Canada Market Research Centre, page 3]

### **d) Horticulture**

Some manufacturers, meanwhile, are directing their GMO research towards decorative items rather than foods. Beverage maker Suntory Ltd., which is working on developing new flower varieties, is one such firm. Suntory took the carnation, which does not naturally contain blue pigment, and inserted a gene for blue pigmentation to produce its "blue carnation." The flower has proven popular with consumers its since 1997 introduction, and annual sales of the blue blossoms have now reached some 500,000 stems.

[*"A New Kind of GMO" Trends in Japan*, [www.jin.jcic.or.jp/trends/honbun/tj000727.html](http://www.jin.jcic.or.jp/trends/honbun/tj000727.html)]

### **e) Functional Foods**

Significant potential exists for collaborative research opportunities in the area of functional foods – foods designed with specific health benefits. Since the population is aging, health and nutrition for later life is an important issue to consumers, and governments are interesting in keeping health costs low.

[*The Food Biotechnology Market in Japan*, The Team Canada Market Research Centre, page 4]

## **VIII. PRACTICAL CONSIDERATIONS IN THE DEVELOPMENT OF MARKETING STRATEGIES FOR CANADIAN AGRI-FOOD SUPPLIERS**

In order to strategize for the future, one must understand and consider the reasons for rejections of GMOs in Japan to date. The following summarizes the key factors, which fueled the negative wave against acceptance of GMOs:

1. Information to the consumers was inadequate and no public acceptance was effectively developed.
2. GMO foods were introduced too quickly and too soon.
3. Too many negative images were presented in reports on GMOs from overseas.
4. Nevertheless, government proceeded in seeking public opinion. The result of which was overwhelmingly negative to GMOs and government responded with mandatory labeling.
5. No food companies wanted to label their products declaring they contained GMO ingredients.
6. There are no visible merits of GMOs in the eyes of Japanese consumers. Had the order of development of GMOs been reversed, and consumers' benefits and needs addressed first, acceptance might have been easier.
7. Consumers were not convinced by the safety assurances offered by government due to lack of trust in administrative bodies.
8. Kirin Breweries announced they would halt their use of GMOs, creating the negative impression of admission by a leading food and beverage company that GMOs are bad.

Mr. Kohmura, executive director of Japan Oilseed Processor Association stated in an interview with myself that public relation activities, combined with the building of public acceptance, are best carried out by the government and the government alone at this point in time. Therefore, he was asking the Canadian oilseed industry not to make any positive promotion of GM canola. He felt such moves would backfire with the consumers, since it would merely highlight the fact that Canadian Canola is GMO. The alternative or counter-argument / strategy is to go all the way promoting GM Canola, but with little chance of winning consumer confidence at present, thereby forcing a

return to non-GMO canola should the promotion not succeed. The industry as a whole should consider both options in order to develop the best long term course of action.

As for other industries in Canada, it is imperative to be aware that the GMO situation in Japan is changing constantly. One is best advised to turn to the Embassy in Japan for balanced, up to date guidance and information regarding the changing regulations. The posts in Japan constantly maintain excellent situation updates through their diplomatic channels.

At the same time, regarding practical business activities, it is always recommended the Canadian companies consult with their buyers and/or the importers in Japan before making any marketing or development changes or decisions.

## IX. CONCLUSIONS

The Japanese government announced for the first time in 1996 the safety assessment of GMO crops.

- It was in the fall of that same year the initial GMO crop shipments from the United States arrived to be marketed in Japan. Consumers' opposition to GMO was unexpectedly strong due to inadequate development of Public Acceptance.
- This in turn led to campaigns boycotting leading beer and beverage manufacturers' products. By 1999, petitions driven by citizens objecting to GMO reached almost three million signatures.
- Influenced by the consumers' strong rejections, the Japanese government adopted the policy of mandatory labeling, slated to start April 1, 2001, as a means of compromise. However, the food manufacturing industries, as well as the distributors/retailers, responded far more quickly than the government with their elimination of GMOs from their product lists and from their shelves.
- Currently, the status of GMOs in Japan has now reached the point where there will be no GMO-labeled products found on store shelves, this long before the start of the mandatory labeling regulations.
- GMOs were introduced too quickly, too soon in Japan, and consumers viewed them as nothing but risks, without offering any merit to speak of.
- Promoters of GMOs, led by the government, are now focusing their GMO research on that which can provide merits to consumers; ones that can be easily understood and more appreciated by the consumers.
- To the government, this building of Public Acceptance for GMOs is going to be a formidable challenge, but one they are determined to accomplish. To help facilitate this effort, they recently announced that information on GMOs would be included in the public school curriculum.

Two Japanese Ministries with English websites covering GMO issues :

- Government of Japan, Ministry of Agriculture, Forestry and Fisheries.  
<http://ss.s.affrc.go.jp/docs/sentan/index.htm>

- Government of Japan, Ministry of Health and Welfare.  
<http://www.mhw.go.jp/english>

## FOOTNOTES

*\* Titles of the Japanese publications translated by the author*

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3. "Watashitachi no Kurashi to Kumikae Shokuhinn" (March, 2000) MAFF Publication : pg. 1. ("Your Life and GMO Foods")
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19. "*The GMO Controversy in Japan*," (April 17, 1998)  
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#### **APPENDICES**

1. "Mandatory Requirement for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques" and "List of the Products Whose Safety Assessment were Reviewed," *Ministry of Health and Welfare*
2. "Labeling System on Genetically Modified Organisms in Japan," *MAFF*
3. "Japanese Import of Major Commodities Affected by GMO," compiled from *Your Life and GMOs*
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6. "Current Status of Commercialization of Transgenic Crop Plants in Japan," *MAFF*
7. "Items Affected by MAFF's Labeling Rules for Foods that Contain GMOs," *MAFF*
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15. GMO Testing Methods Currently in Use in Japan

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## Appendix 1

### Mandatory Requirement for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques

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The Ministry of Health and Welfare has been assessing the safety of foods and food additives produced by recombinant DNA techniques individually based on the "Guideline for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques" (hereinafter referred to as "Guideline for Safety Assessment") since 1991. But the safety assessment of such foods and food additives has been conducted on a voluntary basis at this stage.

In late years, however, such foods and food additives are expected to circulate globally and new types of foods are expected to be developed. The Ministry of Health and Welfare decided to introduce mandatory requirement for safety assessment of such foods and food additives and published relevant announcements to amend existing regulations on 1 May 2000 in order to avoid the distribution of such foods and food additives that has no safety assessment.

According to these announcements, any foods and food additives produced by recombinant DNA techniques that has no safety assessment shall be neither imported nor sold in Japan on and after 1 April 2001.

#### <MATERIALS>

##### MHW Ordinance

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(PDF 5KB)

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(PDF 7KB)

Procedure of Application for Safety Assessment on Foods and Food Additives Produced by Recombinant DNA Techniques (The Announcement No.233, 1 May 2000)  
(PDF 23KB)

Standard for Manufacturing Foods and Food Additives Produced by Recombinant DNA Techniques (The Announcement No.234, 1 May 2000)  
(PDF 32KB)

##### Notice

Amendments to the Specifications and Standards for Foods and Food Additives for Mandatory Requirement of Food and Food Additives Produced by Recombinant DNA Techniques (Notice No.825-1, 1 May 2000)  
(PDF 19KB)

Annex1: Standards for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques  
(PDF 57KB)

Annex2: Procedure of examination conducted by the Minister for Health and Welfare regarding Safety Assessment / Confirmation of Manufacturing Methods of Foods and Food Additives  
(PDF 10KB)

Others (Japanese only)

The Frame of the Specifications and Standards for Foods and Food Additives for Mandatory Requirement of Foods and Food Additives Produced by Recombinant DNA Techniques

<Discussion at the Food Safety Investigation Council>

Report

Report on Mandatory Requirement for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques (Subcommittee on Biotechnology, 21 January 2000)  
(PDF 23KB)

Press Release

A Report from the Subcommittee on Biotechnology about mandatory requirement for "Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques" (21 January 2000)  
(PDF 12KB)

A report submitted by the Food Safety Investigation Council on "Mandatory Requirement for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques" and on "Withdrawal and Readjustment of Designated Food Additives" (25 April 2000)  
(PDF 12KB)

Minutes (Japanese only)

14 December 1999, the Subcommittee on Biotechnology

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# Appendix 1.2

## List of the products whose safety assessment were reviewed

### Food (Crop)

|    | Crop              | Event                                                                            | Trait                | Applicant                     | Date of review | Developer                          |
|----|-------------------|----------------------------------------------------------------------------------|----------------------|-------------------------------|----------------|------------------------------------|
| 1  | Soybean           | Roundup Ready Soybean 40-3-2                                                     | Glyphosate tolerant  | Monsanto Japan Ltd.           | 9/3/96         | Monsanto Company                   |
| 2  | Rapeseed (Canola) | Roundup Ready Canola (RRC73)                                                     | Glyphosate tolerant  | Monsanto Japan Ltd.           | 9/3/96         | Monsanto Company                   |
| 3  | Potato            | NewLeaf Potato (BT6,10,12,16,17,18,23)                                           | Insect resistant     | Monsanto Japan Ltd.           | 9/3/96         | Monsanto Company                   |
| 4  | Corn              | Bt 11                                                                            | Insect resistant     | Monsanto Japan Ltd.           | 9/3/96         | Northrup King Company              |
| 5  | Rapeseed (Canola) | HCN92                                                                            | Glufosinate tolerant | Hoechst Schering              | 9/3/96         | AgrEvo Canada                      |
| 6  | Rapeseed (Canola) | PGS1                                                                             | Glufosinate tolerant | AgrEvo KK<br>Hoechst Schering | 9/3/96         | Incorporated Plant Genetic Systems |
| 7  | Corn              | Event 176                                                                        | Insect resistant     | AgrEvo KK<br>Ciba-Geigy Japan | 9/3/96         | Ciba-Geigy Corporation             |
| 8  | Corn              | YieldGard Corn (Mon810)                                                          | Insect resistant     | Monsanto Japan Ltd.           | 5/26/97        | Monsanto Company                   |
| 9  | Potato            | NewLeaf Potato (Superior/Atlantic) (SPBT02-05,02-07,ATBT04-06,04-30,04-31,04-36) | Insect resistant     | Monsanto Japan Ltd.           | 5/26/97        | Monsanto Company                   |
| 10 | Cotton            | Ingard Cotton (531,757)                                                          | Insect resistant     | Monsanto Japan Ltd.           | 5/26/97        | Monsanto Company                   |
| 11 | Corn              | T14, T25                                                                         | Glufosinate tolerant | Hoechst Schering              | 5/26/97        | Hoechst Schering AgrEvo            |

|    |                      |                                         |                                                      |                                            |          |                                    |
|----|----------------------|-----------------------------------------|------------------------------------------------------|--------------------------------------------|----------|------------------------------------|
| 12 | Rapeseed<br>(Canola) | PHY14,PHY35                             | Glufosinate tolerant                                 | AgrEvo KK<br>Hoechst Schering              | 5/26/97  | Plant Genetic<br>Systems           |
| 13 | Rapeseed<br>(Canola) | PGS2                                    | Glufosinate tolerant                                 | AgrEvo KK<br>Hoechst Schering              | 5/26/97  | Plant Genetic<br>Systems           |
| 14 | Rapeseed<br>(Canola) | PHY36                                   | Glufosinate tolerant                                 | AgrEvo KK<br>Hoechst Schering              | 5/26/97  | Plant Genetic<br>Systems           |
| 15 | Rapeseed<br>(Canola) | T45                                     | Glufosinate tolerant                                 | AgrEvo KK<br>Hoechst Schering              | 5/26/97  | Hoechst<br>Schering AgrEvo<br>GmbH |
| 16 | Cotton               | Roundup Ready Cotton (1445)             | Glyphosate tolerant                                  | AgrEvo KK<br>Monsanto Japan<br>Ltd.        | 12/16/97 | Monsanto<br>Company                |
| 17 | Cotton               | BXN Cotton<br>(10211,10215,10222,10224) | Bromoxynil tolerant                                  | Monsanto Japan<br>Ltd.                     | 12/16/97 | Calgene<br>Incorporated            |
| 18 | Rapeseed<br>(Canola) | MS8RF3                                  | Glufosinate tolerant                                 | Hoechst Schering                           | 12/16/97 | Plant Genetic<br>Systems           |
| 19 | Rapeseed<br>(Canola) | HCN10                                   | Glufosinate tolerant                                 | AgrEvo KK<br>Hoechst Schering              | 12/16/97 | Hoechst<br>Schering AgrEvo<br>GmbH |
| 20 | Tomato               | FLAVR SAVR                              | Flavour saver                                        | AgrEvo KK<br>Kirin Brewery<br>Company Ltd. | 12/16/97 | Calgene<br>Incorporated            |
| 21 | Rapeseed<br>(Canola) | MS8                                     | Glufosinate tolerant<br>Male sterility               | AgrEvo Japan<br>KK                         | 12/14/98 | Plant Genetic<br>Systems           |
| 22 | Rapeseed<br>(Canola) | RF3                                     | Glufosinate tolerant<br>Recovering male<br>sterility | AgrEvo Japan<br>KK                         | 12/14/98 | Plant Genetic<br>Systems           |

|    |                      |                                     |                                             |                                        |          |                                     |
|----|----------------------|-------------------------------------|---------------------------------------------|----------------------------------------|----------|-------------------------------------|
| 23 | Rapeseed<br>(Canola) | WESTAR-Oxy-235                      | Oxynil tolerant                             | Rhone-Poulenc                          | 11/29/99 | Rhone-Poulenc<br>Agrochimie         |
| 24 | Cotton               | Bollgard with BXN Cotton<br>(31807) | Insect resistant                            | Yuka Agro KK<br>Monsanto Japan<br>Ltd. | 11/29/99 | Calgene<br>Incorporated             |
| 25 | Sugar Beat           | T120-7                              | Bromoxynil tolerant<br>Glufosinate tolerant | AgriEvo Japan<br>KK                    | 11/29/99 | Hoechst<br>Schering AgriEvo<br>GmbH |
| 26 | Corn                 | DLL25                               | Glufosinate tolerant                        | Monsanto Japan<br>Ltd.                 | 11/29/99 | Dekalb Genetics<br>Corporation      |
| 27 | Corn                 | DBT418                              | Insect resistant<br>Glufosinate tolerant    | Monsanto Japan<br>Ltd.                 | 11/29/99 | Dekalb Genetics<br>Corporation      |
| 28 | Corn                 | Roundup Ready Corn<br>(GA21)        | Glyphosate tolerant                         | Monsanto Japan<br>Ltd.                 | 11/29/99 | Monsanto<br>Company                 |
| 29 | Rapeseed<br>(Canola) | PHY23                               | Glufosinate tolerant                        | AgriEvo Japan<br>KK                    | 11/29/99 | Plant Genetic<br>Systems            |

#### Food Additives

|   | Product       | Applicant                     | Confirmation Day | Developer            |
|---|---------------|-------------------------------|------------------|----------------------|
| 1 | Chymosin      | Pfizer K.K.                   | 9/5/94           | Pfizer Inc.          |
| 2 | Chymosin      | Robin                         | 9/5/94           | Gist-Brocades N.V.   |
| 3 | Chymosin      | Nosawa & Co. Ltd.             | 9/3/96           | Chr. Hansen A/S      |
| 4 | Alpha-Amylase | Novo Nordisk Bioindustry Ltd. | 5/26/97          | Novo Nordisk A/S     |
| 5 | Riboflavin    | Nippon Roche K.K.             | 12/16/97         | F. Hoffmann-La Roche |



## Appendix 2

### Labeling System on Genetically Modified Organisms in Japan (As translated by MAFF)

#### 1. Details of consideration and future schedule

(1) Japan had started the discussion on labeling requirements for genetically modified foods at the advisory committee on food labeling in May 1997, comprised of representatives of consumers, distributors and producers, and academic circles. The committee deliberated on the issue based on requests from consumers, the actual situation of production, manufacture and distribution, and international trends. It develops its report in August this year.

(2) The Government of Japan decided to bring the labeling requirements recommended by the committee under the JAS Law as amended, immediately entering into the drafting of relevant quality labeling standards. It expects to complete all necessary steps before the issuance of the standards planned for next April, including consultation with the Research Committee for JAS, solicitation of public comments, and notification to WTO. Japan will extend a period of grace for one year after the issuance in next April.

#### 2. Purpose of Labeling

The purpose of labeling is to provide information regarding the use or non-use of GM technologies for better consumers' choice, assuming that genetically modified agricultural products currently marketed and utilized have been assessed for safety by the government.

The labeling does not ever indicate safety nor the difference of safety between GMOs and non-GMO.

#### 3. Foods which may bear indications on genetic modification

Agricultural products having genetically modified varieties that have been assessed for safety by the government, or processed foods thereof (including imported ones), which are supplied for general consumers.

#### 4. Classification of Foods Subject to Labeling Regulations

(1) Foods labeled on genetically modification are classified into three categories from their scientific nature, and concrete labeling methods are developed for each of them in accordance with their scientific nature.

(2) Attached is the summary of labeling requirements that the Government of Japan is planning to implement.

**APPENDIX 2.2**  
**Labeling Requirements for Genetically Modified Foods**  
 (Summary of the report from Subcommittee on  
 Genetically Modified Foods, Food Labeling Committee)

| Classification of food                                                                                                                                                                                                                                                                                                                                 | Item                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Labeling requirement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genetically modified agricultural products and processed foods derived therefrom which are NOT equivalent to conventional foods in composition, nutrient, intended use, etc                                                                                                                                                                            | <Designated foods (plan)?<br>High-oleic-acid soybean and its oil and products derived therefrom (which will be designated after the present safety assessment application have been reviewed)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | - Mandatory labeling ("Soybean [high, oleic acid genetically modified]", etc.)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Agricultural products having genetically modified varieties equivalent to conventional ones in composition, nutrient intended use, etc., (i.e., soybean, corn, potato, [oilseed rape, and cottonseed]) and processed foods derived from these products, in which recombinant DNA or protein produced thereby persists after the manufacturing process. | <Designated foods (plan)>?<br>- Tofu (bean curd) and Tofu products<br>- Kori tofu, bean cured lees, Yuba (sheet of dried soybean casein)<br>- Soybean (for cooking)<br>- Green soybean (edible beans)<br>- Soybean sprouts<br>- Fermented soybeans<br>- Soya milk<br>- Fermented soybean paste<br>- Boiled soybeans<br>- Canned soybeans<br>- Soybean flour<br>- Roast soybeans<br>- Corn snack<br>- Corn starch<br>- Corn (raw)<br>- Popcorn<br>- Frozen / canned corn<br>Food of which main ingredient is any of the above<br>- Potato (raw)<br>- Food of which main ingredient is soybean powder<br>- Food of which main ingredient is plants protein<br>- Food of which main ingredient is corn flour<br>- Food of which main ingredient is corn grits | - Foods made from genetically modified agricultural products<br>-- Labeling required ("Soybean [genetically modified]", "Soybean [genetically modified soybean segregated]", etc)<br><br>- Foods made from agricultural products that is not segregated between GMOs and non-GMOs during the production/distribution process<br>-- Labeling required ("Soybean [genetically modified soybean NOT segregated]", etc)<br><br>- Foods made from non-GMOs that have been segregated from GMOs during the production/distribution process by IP handling<br>-- No labeling required.<br>Possible voluntary labeling (Soybean [not genetically modified]", "Soybean [untransformed variety segregated]", etc.) |

|                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Those processed food derived from agricultural products relative to the kind of crops having genetically modified varieties equivalent to conventional ones in composition, nutrient intended use, etc., (i.e., soybean, corn, potato, oilseed rape, and cottonseed) in which recombinant DNA and protein produced thereby does not exist as a result of removal or decomposition during the manufacturing process.</p> | <ul style="list-style-type: none"> <li>- Soy sauce</li> <li>- Soybean oil</li> <li>- Corn flakes</li> <li>- Corn starch syrup</li> <li>- Isomerized corn syrup</li> <li>- Dextrin</li> <li>- Corn oil</li> <li>- Rapeseed oil</li> <li>- Cottonseed oil</li> <li>- Mashed potato</li> <li>- Potato starch</li> <li>- Potato flakes</li> <li>- Frozen, canned or retort-pouched potato</li> </ul> <p>Food of which main ingredient is any of the above</p> | <ul style="list-style-type: none"> <li>- No labeling required</li> <li>- Possible voluntary labeling (the above criteria is applicable)</li> </ul> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|

1. Soybean, corn potato, oilseed rape, and cottonseed are the safety-approved GMO crops already on the market in Japan.
2. Main ingredient means an ingredients among the top three of all ingredients in weight and 5% or more of the food by weight.
3. IP handling means segregating management system between GMOs and non GMOs through production and distribution in which each handler shall carry out proper segregating management with good management practice and shall issue a verification for proper handling.

## Appendix 4

### Procedure of Application for Safety Assessment Provisional Translation

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#### Ministry of Health and Welfare Announcement No. 233

According to the Specifications and Standards for Foods, Food Additives and Other Related Products (Ministry of Health and Welfare Announcement No.370-December 1954) amended by new Announcement (Announcement No. 232), Procedure of Application for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques is hereby determined as follows.

Even if application is not made based on the provision defined in paragraph 1 of Article 3 of this Announcement, the Minister can examine safety assessment of such foods and food additives, if the Minister has already possessed necessary documents for the safety assessments in applying this Announcement.

1st May, 2000

Minister for Health and Welfare Yuya Niwa

#### Procedures of Application for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques APPLICATION

Article 1. Regarding foods and food additives produced by recombinant DNA techniques, this Announcement determines procedure of application for safety assessment based on the provisions defined in paragraphs 3 and 4 of Part 1, Section A and in Part 2, Section D of the Specifications and Standards for Foods, Food Additives and Other Related Products (Ministry of Health and Welfare Announcement No. 370-Dec.1959).

#### DEFINITION

Article 2. In this Announcement, the term "recombinant DNA techniques" means a technology that DNA cleaved or recombined by, for example, by enzymes, is transferred to living cells for proliferation.

2. In this Announcement, the term "host" means a living cell or an individual organism to which DNA is transferred through recombinant DNA techniques.

3. In this Announcement, the term "vector" means a carrier DNA that transfers the target genes into hosts for proliferation and expression.

4. In this Announcement, the term "inserted gene" means a foreign gene inserted into vectors.

5. In this Announcement, the term "inserted DNA" means a foreign DNA inserted into vectors.

6. In this Announcement, the term "product" means any substance produced by recombinant DNA techniques.

7. In this Announcement, the term "recombinant" means a host containing recombinant DNA.

8. In this Announcement, the term "gene product" means nucleic acid or protein originated by inserted genes.

## **SAFETY ASSESSMENT**

Article 3. When an application document for safety assessment of food or food additive produced by recombinant DNA techniques is submitted by its developer, its agent or other party who can submit appropriate necessary information, the Minister for Health and Welfare shall examine the safety assessment of such food or food additive.

If a food is an organism or made of / made from the organism produced by recombinant DNA techniques or includes such organisms, examination for the safety assessment of such food shall be performed on each organism basis. If foods or food additives are manufactured by use of organisms produced by recombinant DNA techniques or include such organisms, examination for the safety assessment of such foods or food additives shall be performed on each item of such food or food additive basis.

2. The examination for safety assessment designated in the preceding paragraph shall be based on consultation with the Food Safety Investigation Council. If any risk injurious to human health is not found on the assessment, the result of the examination for the safety assessment shall be officially announced.

3. Any person who intends to undergo examination for safety assessment in accordance with first paragraph of this Article shall submit an application form as stated in the attached exhibit together with the information as listed in the appendixes.

#### REASSESSMENT

Article 4. When, due to new scientific findings or any other reasons, it is deemed necessary to reassess safety of the foods and food additives that have already been undergone the examination in accordance with paragraph 2 of the preceding Article, the Minister for Health and Welfare shall reassess safety of such foods and food additives based on consultation with the Food Safety Investigation Council. The results of reassessment shall be officially announced, if any risk injurious to human health is found.

#### DIRECTIONS ON PROGENY CULTIVER

Article 5. Among cultivars prepared by cross hybridization between a conventional cultivar and a recombinant cultivar that has been undergone examination for safety assessment in accordance with the provision stated in preceding Article, paragraph 2, by use of traditional breeding techniques (hereinafter referred to as "progeny cultivar"), if there are certain progeny cultivar that comply with the following requirements, such progeny cultivar can be regarded as the cultivar that has passed the examination based on the identical provision.

1. Properties that are newly acquired through recombinant DNA techniques have not changed in progeny cultivar.
2. Crossbreeding between subspecies has not been performed.
3. There is no change in the amount of ingestion, edible part or processing methods, etc.

-----  
Exhibit Form

(Date)

The Minister for Health and Welfare:

Address (Principal office address for corporate entity)

Name (Corporate name and corporate representative name for corporate entity)

In accordance with "Procedures of Application for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques" (The Ministry of Health and Welfare Announcement No.233 -May 2000), we hereby request for your examination for safety assessment of the attached items:

Foods produced by recombinant DNA techniques  
Food Additives produced by recombinant DNA techniques

Note:

1. Use Japan Industrial Standard A4 size paper
2. Write in block letter with India ink, black ink, etc.

-----  
Appendix 1

#### INFORMATION REQUIRED FOR SAFETY ASSESSMENT WHEN FOODS ARE OR INCLUDE ORGANISMS OBTAINED THROUGH RECOMBINANT DNA TECHNIQUES

##### I. Information Regarding equivalency between Produced Food and Existing Food

1. Information on the genetic materials
2. Information on broad human consumption history
3. Information on nutritional components of foods
4. Information on differences in usage between the conventional variety and the new variety

##### II. Purposes and usage of recombinants

### III. Information Regarding Host

1. Taxonomy (Scientific name, species and strain)
2. Genetic origin
3. Production of harmful physiologically active substances
4. Allergenicity
5. Capability of becoming parasitic and striking root
6. Foreign pathogenic factors (e.g. virus) (a host should not be contaminated with pathogenic exogenous factors.)
7. Ability for survival and propagation under experimental conditions simulating ordinary or natural environments
8. Sexual reproduction cycle and out crossing
9. History of utilization as food
10. Safe consumption
11. Restrictive conditions on survival and proliferation abilities
12. Pathogenicity and production of harmful physiologically active substances in ancestral of related species to the host

### IV. Vector

#### 1. Name and its origin

#### 2. Properties

- (1) DNA molecular weight
  - (2) Cleavage map using restriction enzymes
  - (3) Presence of any potentially harmful nucleic acid sequence
- #### 3. Drug resistance

#### 4. Transmission

#### 5. Host dependency

#### 6. Expression vector preparation method

#### 7. Insertion method and site of the expression vector insertion

### V. Inserted Gene and its Genetic Products

#### 1. Donor

- (1) Name, origin and taxonomy
  - (2) Safety
- #### 2. Method of gene insertion

- (1) Method of vector construction
  - (2) Method of gene insertion
- #### 3. Construction

- (1) Promoter
  - (2) Terminator
  - (3) Hazardous DNA sequence
- #### 4. Properties

- (1) Function of inserted DNA
- (2) Cleavage map using restriction enzymes
- (3) DNA molecular weight

5. Purity

6. Stability

7. Number of inserted gene copies

8. Site, timing and level of gene expression

9. Safety of antibiotic-resistant marker gene

(1) Properties of the gene and gene product

(1) Structure and function

(2) Mechanism of resistance, the method of use and related metabolites

(3) Method of identification and quantification

(4) Changes accompanying cooking or processing (stability against heat and physical pressure)

(5) Changes in gastrointestinal tract environment (stability against acid and digestive enzymes)

(6) Allergenicity

(2) Consumption of genes and their products

(1) Expected amounts of consumption

(2) Present usage of antibiotics associated with resistance

(3) Comparison with normally existing antibiotic-resistant microorganisms

(4) Estimated amount of antibiotics inactivated after oral administration and the possibility that inactivation may cause problems

10. Presence or absence of exogenous open reading frames and the possibility of their transcription and expression

## VI. Recombinants

1. New properties acquired by recombinant DNA techniques

2. Allergenicity of recombinant products (If there is rational reasons, some portions can be omitted.)

(1) Consumption history of the donor

(2) Whether the gene product is known to be an allergen

(3) Sensitivity of the gene product to physicochemical treatment

- (4) Consumption volume of the gene product
- (5) Structural homology of gene products with known food allergens
- (6) Whether the gene product constitutes a considerable part of the total protein intake per day
- (7) Information on binding ability of patient IgE antibody and the gene product relative to allergens with structural homologies to the gene product and information on binding ability of patient IgE antibody and the gene product relative major allergens, if safety is not confirmed on the basis of (1) to (6).
3. Toxicity of recombinant products (other than allergenicity)

4. Effect of recombinant products on metabolic pathways (including information of possibility of reaction with basic properties of existing seeds)

5. Difference from the host (including information of nutrition & anti-nutrition and information of changes in composing elements that may be potentially harmful after changes in content volume)

6. Survival and proliferation in the external environment

7. Restrictive conditions on survival and proliferation abilities of recombinants

8. Inactivation method of recombinants

9. Approval and usage as food in other countries

10. Methods of preparation, breeding and cultivation

11. Methods of seed production and management

VII. Information regarding results of the following studies (The results shall be obtained by studies performed at a GLP (Good Laboratory Practice) compliant facilities following GLP standard) if safety assessment can not be accomplished from the information listed in II through VI (If there is rational reasons, a portion or the entire set of studies can be exempted):

1. Acute toxicity study

2. Sub acute toxicity study
3. Chronic toxicity study
4. Reproduction study
5. Mutagenicity study
6. Carcinogenicity study
7. Other necessary studies (e.g. intestinal tract toxicity, immunological toxin, neurological toxicity, nutrition etc.)

#### Appendix 2.

### INFORMATION REQUIRED FOR SAFETY ASSESSMENT WHEN FOODS AND FOOD ADDITIVES ARE MANUFACTURED BY USE OF LIVING ORGANISMS OBTAINED THROUGH RECOMBINANT DNA TECHNIQUES

#### I. Substantial equivalence between produced substances and existing substances

#### II. Recombinants

##### 1. Confirmation that a non-pathogenic recombinant can be utilized in GILSP or Category

1 manufacturing (see "Ministry of Health and Welfare Announcement No. 234")

##### 2. Purpose and usage of recombinants

##### 3. Host

- (1) Taxonomy (scientific name, stain name)
  - (2) Production of pathogens or harmful physiologically active substances
  - (3) Parasiticity and specificity
  - (4) Foreign pathogenic factors (e.g. virus) (a host should not be contaminated with pathogenic exogenous factors)
  - (5) Survival and proliferation abilities under experimental conditions simulating ordinary or natural environments
  - (6) Sexual or asexual reproduction cycle and cross reactivity on sexual life cycle
  - (7) History of utilization as food
  - (8) Restrictive conditions on survival and proliferation abilities
  - (9) Pathogenicity and production of harmful physiologically active substances of host-related strains
4. Vector

- (1) Name and origin
  - (2) Properties
    - (1) DNA molecular weight
    - (2) Cleavage map using restriction enzymes
    - (3) Presence of any potentially harmful nucleic acid sequence
    - (3) Drug resistance
    - (4) Transmission to other species
    - (5) Host dependency
    - (6) Preparation method of expression vector
    - (7) Insertion method and site of the expression vector
5. Inserted gene and its gene product

- (1) Name, origin, and taxonomy of donor
- (2) Method of gene insertion
  - (1) Method of vector construction
  - (2) Method of gene insertion
  - (3) Construction
    - (1) Promoter
    - (2) Terminator
    - (3) Hazardous DNA sequence
  - (4) Properties
    - (1) Function of inserted DNA
    - (2) Cleavage map using restriction enzymes
    - (3) DNA molecular weight
    - (5) Purity on DNA sequences
    - (6) Safety of antibiotic-resistant makers
  - (1) Properties of the gene and gene product:
    - \*Structure and function

- \*Expression mechanism of resistance, the method of use and related metabolites
  - \*Method of identification and quantification
  - \*Changes accompanying cooking or processing (stability against heat and physical pressure)
  - \*Changes in gastrointestinal tract environment (stability against acid and digestive enzymes)
  - \*Allergenicity
  - (2) Consumption of genes and their products:
    - \*Estimated amounts of consumption
    - \*Present usage of antibiotics associated with resistance
    - \*Comparison with existing antibiotic resistance
    - \*Estimated amount of antibiotics inactivated after oral administration and the possibility that cause any problem by inactivation process
  - (7) Presence or absence of exogenous open reading frames and the possibility of their transcription and expression
6. Recombinants

- (1) New properties acquired by recombinant DNA techniques (must be non-pathogenic)
  - (2) Survival and proliferation in the external environments
  - (3) Restrictive conditions on survival and proliferation abilities
  - (4) Inactivation method of recombinants
  - (5) Difference from the host
- III. Miscellaneous ingredients and manufacturing apparatus other than the recombinant

1. The history of the actual use as a manufacturing apparatus on manufacturing process or as raw ingredients for foods or food additives.
2. Existing knowledge regarding its safety in use as a manufacturing apparatus or ingredients for foods or additives.

#### IV. Products

1. Absence of contamination by recombinants
2. Purity and amounts of impurity
3. Purifying process

4. Changes in levels of normal ingredients which may be harmful

5. Approval status and usage of products in other countries

Information regarding results of the following studies

(The results shall be obtained by studies performed at a GLP (Good Laboratory Practice) compliant facilities following GLP standard) if safety assessment can not be fully accomplished from the information listed in II through VI (If there is rational reasons, a portion or the entire set of studies can be exempted): )

1. Acute toxicity study

2. Sub acute toxicity study

3. Chronic toxicity study

4. Reproduction study

5. Mutagenicity study

6. Carcinogenicity study

7. Other necessary studies (e.g. intestinal tract toxicity, immunological toxin, neurological toxicity etc.)

Note: This English version of the Notice is translated to meet the need of the non-Japanese speaking people. In the case of any discrepancy between the Japanese original and the English translation, the former will take priority.

## Appendix 5

### System and Procedures for the Application of recombinant DNA Crop plants in Agriculture, Forestry, Fisheries and the Food Industry (Introduction to Japanese Government Guidelines Regarding recombinant DNA Crop Plants)

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#### 1. Introduction

The Organization for Economic Cooperation and Development (OECD) and other bodies are currently preparing an international framework for the application of recombinant DNA (hereafter referred to as "rDNA") organisms in various agricultural and industrial uses. In this connection, the Japanese government has already established certain guidelines for the safety assessments of the application of rDNA crop plants in agriculture, forestry, fisheries and the food industry. These guidelines cover the following cases:

The domestic cultivation of rDNA crop plants, or the import of such crop plants which may propagate in a natural environment.

rDNA crop plants to be used in the manufacture of feed products.

rDNA crop plants to be used in the manufacture of food products.

As these guidelines apply to rDNA crop plants developed in foreign countries, the Ministry of Agriculture, Forestry and Fisheries (MAFF), and the Ministry of Health and Welfare (MHW) are receiving an increasing number of inquiries from overseas companies.

The purpose of this leaflet is to present an outline of the system and procedures established by the Japanese government for the safety assessments of the application of rDNA crop plants in agriculture, forestry, fisheries and the food industry.

(Note; that procedures differ for microorganisms and animals.)

#### 2. Historical Background of Safety assessments of rDNA Crop plants

##### (1) Historical Background

With the start of rDNA experiments in the United States in 1973, scientists pointed to several hypothetical risks associated with such experimentation. The concern was expressed that genetic engineering may lead to the generation of unexpected life forms, or that the rDNA organisms could eventually defy human control. Because this science was in its infancy at the time, no concrete data were available to prove that these hypothetical fears were unfounded. An international discussion ensued on the conditions for conducting rDNA experiments with various countries eventually establishing their

own guidelines for experimentation in this field. The National Institute of Health (NIH) of the United States led the world in publishing its "Guidelines for rDNA Experiments" in 1976. Japan and other advanced countries have adopted various guidelines which are essentially the same as the NIH guidelines.

The consideration of guidelines for industrial applications of rDNA organisms was initiated in 1983 by the OECD's Committee for Science and Technological Policy (CSTP). In 1986, the OECD Council presented the member countries with a recommendation for a basic framework for safety assessments. Furthermore, an agreement was reached by 1993 on the framework in evaluating the environmental impact of rDNA organisms and in carrying out safety assessments for application in foodstuffs. Based on these recommendations and agreements, individual countries have enacted related laws and formulated safety assessment systems based on their current guidelines. "The Guidelines for Application of rDNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries" which is introduced in this leaflet represents a system which was formulated in this process.

## (2) Basic Concepts and Principles

The OECD agreement on safety assessments is based on the following two important fundamental scientific principles.

### 1) the concept of "Familiarity"

"Familiarity" is introduced in the OECD report of "Safety Considerations for Biotechnology: Scale-up of Crop Plants".

"Familiarity" refers to the availability of sufficient knowledge and experience needed to analyze the risks/safety of a larger scale test in a given environment involving new plant variety, such as rDNA crop plants. In other words, under the principle of "Familiarity" sufficient knowledge and experience for managing the introduction of crop plants should be on hand before proceeding to the next proposed scale-up.

What this means in the case of rDNA crop plants is that cultivation of a novel plant in ordinary field is predicated on the existence of sufficient knowledge and experience to assess that this cultivation will not have a negative ecological and environmental impact.

### 2) the concept of "Substantial Equivalence"

"Substantial Equivalence" refers to the consideration of assumption of safety of new foods as rDNA crop plants comparative to the traditional counterpart. This provides also what aspects of the product, if any, require further study. The establishment of "Substantial Equivalence" requires confirmation of the well-characterization of the newly introduced traits and conclusion that there is reasonable certainty of no harm as compared with its conventional or traditional counterpart, based on a consideration of the factors (factors affecting the environment, such as hybridizing capacity, pollen dispersion, wintering properties, as well as food-safety factors, such as nutrient

composition, toxicity of genetic materials, and allergenic properties).

### 3. Procedures to be Taken by Overseas Companies Intending to Apply rDNA Crop Plants in Japan

#### (1) Japanese Guidelines Concerning rDNA Organisms

Before going into the explanation of the "Guidelines for Application of rDNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries," a brief description will be given of the overall Japanese guidelines regarding rDNA organisms. Currently, two guidelines have been established for experimentation and six guidelines are in force for industrial application.

#### 1) Guidelines for Experimental Activities

"Guidelines for rDNA Experimentation in University Research Facilities"  
(Ministry of Education (MONBU) Guideline)

"Guidelines for rDNA Experimentation" (guidelines for experimentation in all research facilities other than university facilities)

(Science and Technology Agency (STA) Guideline)

#### 2) Guidelines for Industrial Application

"Guidelines for Application of rDNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries"  
(Guideline for rDNA Organisms [MAFF])

"Guidelines for Safety assessments of Application of rDNA Organisms in Feed"  
(Guideline for Feed [MAFF])

"Guidelines for Safety assessments of Application of rDNA Organisms in Feed Additives"  
(Guideline for Feed Additives [MAFF])

"Guidelines for Foods and Food Additives Produced by the rDNA Techniques"  
(Guideline for Foods [MHW])

Guidelines for the Manufacture of Pharmaceuticals, Etc., Utilizing rDNA Technology"  
(Guideline for Pharmaceuticals [MHW])

"Guidelines for the Industrialization of RDNA Technology"

(Ministry of International Trade and Industry (MITI) Guideline)

Any person or organization (developer) which wishes to utilize rDNA crop plants in agriculture, forestry, fisheries and the food industry must conduct safety assessments in accordance with the following guidelines as they pertain to the proposed purpose and method of application.

Guidelines for evaluating the ecological and environmental effects of cultivation.  
(Guideline for rDNA Organisms [MAFF])

Guidelines for application in food and food additives. (Guideline for Foods [MHW])

Guidelines for application in feed and feed additives. (Guideline for Feed [MAFF])

When a safety assessments has been conducted in accordance with the relevant guidelines, the developer may request the responsible government minister to approve the safety criteria regarding safety assessment and procedures utilized to ensure compliance with that guideline.

3) Guidelines for Application of rDNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries

The purpose of these guidelines is to establish basic requirements concerning the appropriate application of rDNA organisms in agriculture, forestry, fisheries, and the food industry, as well as in other related industries which come under the jurisdiction of the Ministry of Agriculture, Forestry and Fisheries (hereafter referred to as "agro-industries"), so as to assure the safe use of rDNA organisms and to achieve the sound overall development of agro-industries. These guidelines cover all rDNA organisms (crop plants, microorganisms, and small laboratory animals) to which new properties have been introduced using rDNA technology.

In order to utilize a rDNA plant, it must be confirmed that the plant will not have a new impact on the agriculture and ecology of Japan. The guidelines distinguish between two separate stages of application, namely: application in a simulated model environment, and application in an open system.

Before undertaking to apply a rDNA plant in either a simulated model environment or an open system, the developer must request the approval of the Minister of Agriculture, Forestry and Fisheries confirming that the safety assessments satisfies the requirements of the guidelines.

Application in a Simulated Model Environment

In this stage, the rDNA plant is experimentally cultivated in a simulated model environment (confined field test) in order to investigate its properties as an agricultural

product, including weediness and hybridizing potential with biological relative species. If the developer does not have access to the confined field necessary for undertaking the experiment, the developer must apply for the use of the experimentation facilities of the Ministry of Agriculture, Forestry and Fisheries.

Based on the results of field tests conducted in a simulated model environment, a safety assessments will be undertaken to determine whether the rDNA plant will have a new impact on the agriculture and ecology of Japan.

#### Application in an Open System

When the safety of a rDNA plant is ensured in a simulated model environment as outlined in Section [1] above and complied by MAFF, cultivation in a field for general agricultural products will be available in Japan. In the case of flowers and trees, immediate commercialization will be possible at this stage.

#### (2) Specific Procedures

##### 1) rDNA plant experiments to be conducted in Japan

The STA Guidelines apply to cases in which rDNA crop plants are imported into Japan for use in rDNA experiments involving the introduction of new genetic materials. Such experiments and cultivation must be conducted in contained conditions which are appropriate to the type of host cells, vectors and donor DNAs to be used.

2) Export of rDNA crop plants intended for domestic cultivation of breeding materials, or export of seeds or other cultivable forms. In the case of edible oil seeds for which there is a possibility of natural propagation in Japan, breeding materials intended for cultivation in a general agricultural condition must undergo safety assessments in accordance with the Guidelines for rDNA Organisms [MAFF] even if safety assessments have been completed abroad. This is because of the differences in propagating and environmental conditions in Japan and abroad, and because of Japan's limited experience in the industrial application of rDNA crop plants.

If the safety of a rDNA plant has already been complied in Japan, it is not necessary to undertake a safety assessments again of any progeny obtained by conventional crossing the rDNA crop plants with other varieties.

go to "Current Status of Commercialization of Transgenic Crop Plants in Japan"

3) Export of rDNA crop plants intended for direct consumption as food or feed, or export of food or feed containing rDNA crop plants

These cases are subject to the pertinent safety assessments guidelines, namely: Guidelines for Foods [MHW], Guidelines for Feed [MAFF], and Guideline for Feed Additives [MAFF].

Regarding these cases, please consult the following government offices.

For use as food: Food Sanitation Division, Environmental Health Bureau, Ministry of Health and Welfare.

For use as foodstuff additive: Food Chemistry Division, Environmental Health Bureau, Ministry of Health and Welfare.

For use as feed: Commercial Feed Division, Livestock Industry Bureau, Ministry of Agriculture, Forestry and Fisheries.

For use as feed additive: Animal Health Division, Livestock Industry Bureau, Ministry of Agriculture, Forestry and Fisheries.

#### 4. Conclusion

The commercial use of rDNA crop plants cannot proceed smoothly without the understanding of the consumers. By the same token, the promotion of public understanding and recognition is an indispensable element in the future development of bio-technology. Genetically engineered agricultural products are now entering the stage of commercial application. In this context, adherence to the carrying out of safety assessments which are spelled out in the various existing safety assessments guidelines in Japan constitute the optimal method for gaining the understanding of the Japanese consumer.

Various measures have been taken to cope with these inquiries. On December 20, 1995 the Society for Techno-Innovation Agriculture, Forestry and Fisheries (STAFF) established the "Information Desk for the Application of rDNA Organisms", responding to the request of MAFF, with an aim to supplying pertinent information on this subject and for providing overseas companies with opportunities for consulting. For more information concerning this leaflet, please contact the following:

Information Desk for the Application of rDNA Organisms  
STAFF  
Sankaido Building 7 Floor  
Akasaka 1-9-13  
Minato-ku, Tokyo 107  
Telephone: Int. 3-3586-8644  
Facsimile: Int. 3-3586-8277

Innovative Technology Division  
Research Council Secretariat  
Ministry of Agriculture, Forestry and Fisheries  
Kasumigaseki 1-2-1  
Chiyoda-ku, Tokyo 100

Telephone: Int. 3-3502-3919  
Facsimile: Int. 3-3502-4028

## Appendix 6

### Current Status of Commercialization of Transgenic Crop Plants in Japan

March - 10 - 2000

Following crop plants were complied the safety assessments with the guidelines required in Japan.

---

#### Example:

Crop name with phenotypic category(line name)

Institution/Company: Developer of the original transgenic crop

Organism: Recipient crop

Phenotype: Phenotype

Gene: Genes expressed in the crop

Purpose: Application purposes in Japan

Compliance: month and year of administrative decision in environmental, food and feed aspects,

- not be complied with Guidelines yet , X ;out of object in the Guidelines

---

..Herbicide Tolerant Soybean(40-3-2)

Institution/Company: Monsanto

Organism: Soybean

Phenotype: Glyphosate tolerant

Gene: EPSPS

Purpose: Breeding Material, Food, Feed

Compliance:(Environment; March, 1996)

(Food; September, 1996)

(Feed; September, 1996)

---

..Herbicide Tolerant Canola(HCN92)

Institution/Company: AgrEvo

Organism: Canola

Phenotype: Gluphosinate tolerant

Gene: Phosphinothricin acetyltransferase, NPT II

Purpose: Food, Feed

Compliance: (Environment; March, 1996)  
(Food; September, 1996)  
(Feed; September, 1996)

..Herbicide Tolerant Canola(PGS1)  
Institution/Company:Plant Genetic Systems  
Organism: Canola  
Phenotype: Hybrid, Gluphosinate tolerant  
Gene: bar, male sterile, fertile restoration, NPT II  
Purpose: Food, Feed  
Compliance: (Environment; March, 1996)  
(Food; September, 1996)  
(Feed; September, 1996)

..Herbicide Tolerant Canola(GT73)  
Institution/Company: Monsanto  
Organism: Canola  
Phenotype: Glyphosate tolerant  
Gene: EPSPS, Glyphosate Oxidoreductase  
Purpose: Breeding Material, Food, Feed  
Compliance: (Environment; March, 1996)  
(Food; September, 1996)  
(Feed; September, 1996)

..Lepidoptera Resistant Corn(Event 176)  
Institution/Company: Ciba-Geigy  
Organism: Corn  
Phenotype: Lepidoptera resistant  
Gene: Bt (CryIA(b)), PAT  
Purpose: Food, Feed  
Compliance: (Environment; October, 1996)  
(Food; September, 1996)  
(Feed; September, 1996)

..Lepidoptera Resistant Corn(Bt11)  
Institution/Company: Northrup King  
Organism: Corn  
Phenotype:Lepidoptera resistant  
Gene:Bt (CryIA(b)), PAT  
Purpose:Food, Feed  
Compliance:(Environment; October, 1996)  
(Food; September, 1996)  
(Feed; September, 1996)

..Coleoptera Resistant Potato(New Leaf Potato)

Institution/Company:Monsanto

Organism:Potato

Phenotype:Coleoptera resistant

Gene:Bt (CryIIIA), NPT II

Purpose:Food

Compliance:(Environment; X )

(Food; September, 1996)

..Lepidoptera Resistant Corn(Yield Guard Corn:MON810)

Institution/Company:Monsanto

Organism:Corn

Phenotype:Lepidoptera resistant

Gene:Bt (CryIA(b))

Purpose:Food,Feed

Compliance:(Environment; October, 1996)

(Food; May, 1997)

(Feed; June, 1997)

..Coleoptera Resistant Potato(New Leaf Potato)

Institution/Company:Monsanto

Organism:Potato

Phenotype:Coleoptera resistant

Gene:Bt (CryIIIA), NPT II

Purpose:Food

Compliance:(Environment; X)

(Food; May, 1997)

...Lepidoptera Resistant Cotton(Ingard Cotton)

Institution/Company:Monsanto

Organism:Cotton

Phenotype:Lepidoptera resistant

Gene:Bt (CryIA(c))

Purpose:Food, Feed

Compliance:(Environment; April, 1997)

(Food; May, 1997)

(Feed; June, 1997)

...Herbicide Tolerant Corn(T14,T25)

Institution/Company:AgroEvo

Organism: Corn  
Phenotype: Gluphosinate tolerant  
Gene: Phosphinothricin acetyltransferase (pat)  
Purpose: Food, Feed  
Compliance: (Environment; December, 1997)  
(Food; May, 1997)  
(Feed; March, 1997)

...Herbicide Tolerant Canola (PHY14, PHY35)  
Institution/Company: Plant Genetic Systems  
Organism: Canola  
Phenotype: Hybrid, Gluphosinate tolerant  
Gene: bar, male sterile, fertile restration, NPT II  
Purpose: Food, Feed  
Compliance: (Environment; August, 1997)  
(Food; May, 1997)  
(Feed; January, 1998)

...Herbicide Tolerant Canola (PGS2)  
Institution/Company: Plant Genetic Systems  
Organism: Canola  
Phenotype: Hybrid, Gluphosinate tolerant  
Gene: bar, male sterile, fertile restration, NPT II  
Purpose: Food, Feed  
Compliance: (Environment; April, 1997)  
(Food; May, 1997)  
(Feed; June, 1997)

...Herbicide Tolerant Canola (PHY36)  
Institution/Company: Plant Genetic Systems  
Organism: Canola  
Phenotype: Hybrid, Gluphosinate tolerant  
Gene: bar, male sterile, fertile restration, NPT II  
Purpose: Food, Feed  
Compliance: (Environment; August, 1997)  
(Food; May, 1997)  
(Feed; June, 1997)

...Herbicide Tolerant Canola (T45)  
Institution/Company: AgrEvo  
Organism: Canola  
Phenotype: Hybrid, Gluphosinate tolerant

Gene:pat,  
Purpose:Food, Feed  
Compliance:(Environment; April, 1997)  
(Food; May, 1997)  
(Feed; June, 1997)

...Herbicide Tolerant Cotton(Roundup Ready Cotton)  
Institution/Company:Monsanto  
Organism:Cotton  
Phenotype:Glyphosate tolerant  
Gene:EPSPS, NPT II  
Purpose:Breeding Material, Food  
Compliance:(Environment; December, 1997)  
(Food; December, 1997)  
(Feed; January, 1998)

...Herbicide Tolerant Cotton(BXN Cotton)  
Institution/Company:Calgene  
Organism:Cotton  
Phenotype:Bromoxynil tolerant  
Gene:BXN, NPT II  
Purpose:Breeding Material, Food  
Compliance:(Environment; December, 1997)  
(Food; December, 1997)  
(Feed; January, 1998)

...Herbicide Tolerant Canola(MS8RF3)  
Institution/Company:Plant Genetic Systems  
Organism:Canola  
Phenotype:Hybrid, Gluphosinate tolerant  
Gene:bar, male sterile, fertile restration, NPT II  
Purpose:Food, Feed  
Compliance:(Environment; July, 1998)  
(Food; December, 1997)  
(Feed; January, 1998)

...Herbicide Tolerant Canola(HCN10)  
Institution/Company:AgrEvo  
Organism:Canola  
Phenotype:Hybrid, Gluphosinate tolerant  
Gene:pat.,NPT II  
Purpose:Food, Feed

Compliance:(Environment; November. 1997)  
(Food; December, 1997)  
(Feed; January, 1998)

...Ripening Delayed Tomato  
Institution/Company:Calgene  
Organism:Tomato  
Phenotype:Ripening Delayed  
Gene:ACC, NPT II  
Purpose:Breeding Material, Food  
Compliance:(Environment; April, 1996)  
(Food; December, 1997)

...Herbicide Tolerant Canola(MS8)  
Institution/Company:Plant Genetic Systems  
Organism:Canola  
Phenotype:Gluphosinate tolerant  
Gene:PAT, male sterile  
Purpose:Breeding Material, Food, Feed  
Compliance:(Environment; -)  
(Food; December, 1998)  
(Feed; February, 1999)

...Herbicide Tolerant Canola(RF3)  
Institution/Company:Plant Genetic Systems  
Organism:Canola  
Phenotype:Gluphosinate tolerant  
Gene:PAT, fertility restoration  
Purpose:Breeding Material, Food, Feed  
Compliance:(Environment; -)  
(Food; December, 1998)  
(Feed; February, 1999)

...Herbicide Tolerant Canola(WESTAR-Oxy-235)  
Institution/Company:Rhone-Poulenc  
Organism:Canola  
Phenotype:Bromoxynil tolerant  
Gene:BXN  
Purpose:Food, Feed  
Compliance:(Environment; July, 1998)  
(Food; November, 1999)  
(Feed; December, 1999)

...Lepidoptera Resistant and Herbicide Tolerant Cotton(Bollgard with BXN Cotton :31807)

Institution/Company:Calgene

Organism:Cotton

Phenotype:Lepidoptera resistant, Bromoxynil tolerant

Gene:Bt(CryIA), BXN

Purpose:Food, Feed

Compliance:(Environment; December, 1998)

(Food; November, 1999)

(Feed; December, 1999)

...Herbicide Tolerant Sugar Beet(T120-7)

Institution/Company:AgrEvo

Organism:Sugar Beet

Phenotype:Glufosinate.tolerant

Gene:PAT

Purpose:Food

Compliance:(Environment; X)

(Food; November, 1999)

(Feed; December, 1999)

...Herbicide Tolerant Corn(DLL25)

Institution/Company:Dekalb

Organism:Corn

Phenotype:Glufosinate.tolerant

Gene:PAT

Purpose:Food, Feed

Compliance:(Environment; June, 1999)

(Food; November, 1999)

(Feed; March, 2000)

...Lepidoptera Resistant and Herbicide Tolerant Corn(DBT418)

Institution/Company:Dekalb

Organism:Corn

Phenotype:Lepidoptera resistant, Glufosinate.tolerant

Gene:Bt(CryIA(c)), PAT

Purpose:Food, Feed

Compliance:(Environment; June, 1999)

(Food; November, 1999)

(Feed; -)

...Herbicide Tolerant Corn(GA21)

Institution/Company:Monsanto

Organism:Corn

Phenotype:Glyphosate.tolerant

Gene:EPSPS

Purpose:Food, Feed

Compliance:(Environment; December, 1998)

(Food; November, 1999)

(Feed; December, 1999)

...Herbicide Tolerant Canola(PHY23)

Institution/Company:Plant Genetic Systems

Organism:Canola

Phenotype:Glufosinate.tolerant

Gene:PAT, male sterile, fertile restration

Purpose:Food, Feed

Compliance:(Environment; August, 1997)

(Food; November, 1999)

(Feed; February, 1999)

(Note: Plant pathogens cause import ban of living potato and beet from USA, therefore these plants do not satisfy requirements of the guidelines for environmental effects and safety of feed.)

Innovative Technology Division.Research Council Secretariat

Ministry of Agriculture, Forestry and Fisheries

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## Appendix 7

### GMO Information

#### Items Affected by MAFF's Labeling Rules for Foods that Contain GMOs:

1. Tofu (fresh bean curd) and aburage (fried bean curd)
2. Frozen tofu, okara (bean curd lees) and yuba (dried bean curd sheets)
3. Natto (fermented soybeans)
4. Soybean milk
5. Miso (fermented soybean paste)
6. Boiled soybeans
7. Canned and bottled soybeans
8. Soybean flour
9. Roasted soybeans
10. Foods with No. 1 through No. 9 as a major ingredient
11. Foods with Soybeans for cooking as a major ingredient
12. Foods with soy protein as a major ingredient
13. Foods with soy protein as a major ingredient
14. Foods with edamame (green soybeans in the shell as a major ingredient)
15. Foods with soybean sprouts as a major ingredient
16. Corn for snacks and crackers
17. Corn starch
18. Popcorn
19. Frozen corn
20. Canned and bottled corn
21. Foods with corn flour as a major ingredient
22. Foods with corn grits as a major ingredient (except corn flakes)
23. Foods with corn for cooking as a major ingredient
24. Foods with No. 16 through No. 20 as a major ingredient

#### Items exempt from the labeling rules:

1. Soybean oil
2. Soy sauce
3. Corn oil
4. Corn Flakes
5. Glucose syrup
6. High-fructose corn syrup
7. Alcoholic beverages made from corn starch
8. Dextrin
9. Rapeseed oil
10. Cotton seed oil
11. Mashed potatoes
12. Potato starch
13. Potato flakes
14. Frozen, canned or retort-packed potato products

Transgenic Crop Plants that have been approved (as of December 31, 1999) for commercialization in Japan under the Japanese ...

Herbicide-tolerant soybean (1)  
Herbicide-tolerant canola (13)  
Herbicide-tolerant corn (3)  
Herbicide-tolerant cotton (2)  
Herbicide-tolerant sugar beet (1)  
Coleopteran-resistant potato (2)  
Lepidopteron-resistant corn (3)  
Resistant-resistant cotton (1)  
Resistant-resistant and herbicide-tolerant cotton (1)  
Resistant-resistant and herbicide-tolerant corn (1)  
Ripening-delayed tomato (1)

## Appendix 8

### **Genetically Modified Food Labeling Standard** **Ministry of Agriculture, Forestry and Fisheries** (UNOFFICIAL TRANSLATION )

#### **Article 1. Scope.**

This standard applies to processed foods and to perishable foods.

#### **Article 2. Definitions**

Term/definition

-

**Designated agricultural products:** Agricultural products which have some crops developed by recombinant DNA techniques in their category and are listed in Attached Table 1. (Recombinant DNA techniques is a technological method of dividing DNA and recombining them using enzymes , etc ., and transplanting the recombinant DNA into live cells for propagation. Same applies hereinafter. )

**Genetically modified agricultural products :** Agricultural products obtained through recombinant DNA techniques.

-

**Non-GM agricultural products:** Agricultural products that belong to the category of designated agricultural products but are not genetically modified agricultural products themselves.

-

**Identity preserved handling :** Management method in which segregation between genetically modified agricultural products and non-GM agricultural products is accomplished, under the care of a good manager at each stage of production, distribution and processing. Further, it must be verified by using documents clearly indicating that segregation has been made.

-

**Main ingredients:** Ingredients that are ranked within the top three constituents in terms of the ratio of weight they occupy, and the weight ratios of which account for five or more percent of the total.

#### **Article 3. Labeling method**

1. For foods processed from designated agricultural products (including foods subsequently processed from such foods) listed in the left column of Attached Table 2 as the products in which recombinant DNA or the resulting protein still exists even after processing, the following declarations are required:

- Producers, manufacturers, packers or importers (or retailers when retailers are nominated to do the labeling based on the agreement with the producers, manufacturers, and packers) must indicate the following information on the container or the package of the designated agricultural products listed in the right column of Attached Table 2 as well as the items required by Article 4 of the Processed Food Quality Labeling Standard.

This obligation, however, may not be applied when the labeling space of the containers or packages of the products is 30 cm<sup>2</sup> or less in size.

(1) In the event that a ingredient is a genetically modified agricultural product and it is confirmed that it has been treated under a identity preserved handling; Regardless of the provision of 6 of Article 3 of the Processed Food Quality Labeling Standard, it shall be declared that the ingredient is a genetically modified agricultural product by printing in parentheses words representing genetically modified following the name of the ingredient.

(2) In the event that a ingredient is a designated agricultural product and if the product has been produced, distributed, or processed without segregation between genetically modified agricultural products and non-GM agricultural products; Regardless of the provision of 6 of Article 3 of the Processed Food Quality Labeling Standard, it shall be declared that such segregation has not been made for the ingredient by printing in parentheses words representing GM not segregated following the name of the ingredient.

-

(3) In the event that a ingredient is a non-GM agricultural product and it is confirmed that it has been treated under a identity preserved handling:

- The name of the ingredient shall be declared; or
- (In the case that it is made of only one ingredient) the name of the ingredient should be omitted with respect to the provision of 6 of Article 3 of the Processed Food Quality Labeling Standard; or
- It shall be declared that the ingredient is a non-GM agricultural product treated under a identity preserved handling by printing in parentheses words representing non-GM following the name of the ingredient.

-

2. As for the labeling of designated agricultural products, following declarations are required for the retailers in addition to the items which are required by Articles 4 of the Perishable Food Quality Labeling Standard.

-

(1) In the event that the genetically modified agricultural product is confirmed that it has been treated under a identity preserved handling; It shall be declared that the designated agricultural product is a genetically modified agricultural product by printing in parentheses words representing genetically modified following the name of the food.

-

(2) In the event that the bag perishable food is a designated agricultural product and if the product has been produced or distributed without segregation between genetically modified agricultural and non-GM agricultural products; It shall be declared that segregation has not been made for the perishable food by printing in parentheses words representing GM not segregated following the name of the perishable food.

-

(3) In the event that the non-GM agricultural product is confirmed that it has been treated under a identity preserved handling:

- The name of the agricultural product shall be declared; or
  - It shall be declared that the perishable food is a non-GM agricultural product treated under a identity preserved handling, by printing in parentheses words representing non-GM following the name of the designated agricultural products.
- 

3. Although a identity preserved handling has been performed, there is a possibility that a certain amount of genetically modified agricultural products may be unintentionally commingled into non-GM one. In this case, as far as the confirmation procedures provided for in 1(1), 1(3), 2(1), and 2(3) of this Article have been properly followed, the products shall be regarded as the products treated under a identity preserved handling for the application of 1 or 2 of this Article.

-

#### **Article 4. Processed Foods Not requiring Labeling**

-

For foods listed in Attached Table 2 which contain designated agricultural products but are not main ingredients, the labeling concerning GM is not necessary. However, the provisions of 1 and 3 of this Article 3 can be applied to ingredients that are designated agricultural products or the processed food which is made of designated agricultural products, if the products carry labeling concerning GM.

2. For processed foods not listed a Attached Table 2. the labeling concerning GM is not necessary. However, the provisions of 1 and 3 of Article 3 can be applied to ingredients that are designated agricultural products, if the products carry labeling concerning GM.

-

#### **Article 5. Labeling Prohibitions**

-

Article 6 of the Processed Food Quality Labeling Standard and of the Perishable Food Quality Labeling Standard provide for the words that must not be printed on processed foods and perishable foods, respectively. In addition, no words representing non-GM shall appear either on agricultural products that belong to crop items other than those which were developed by recombinant DNA techniques or on foods processed from such products.

Table 1 (Related to Article 2)

1. Soybean (including green soybeans and soybean sprouts)
2. Corn
3. Potato
4. Rapeseed
5. Cottonseed

Table 2 (Related to Article 3)

| Items subject to labeling                                       | Ingredient to be labeled |
|-----------------------------------------------------------------|--------------------------|
| 1. Tofu (soybean curd) and fried tofu                           | Soybean                  |
| 2. Dried soybean curd, soybean refuse, yuba                     | Soybean                  |
| 3. Natto (fermented soybean)                                    | Soybean                  |
| 4. ToOnyu (soy milk)                                            | Soybean                  |
| 5. Miso (soybean paste)                                         | Soybean                  |
| 6. Cooked soybean                                               | Soybean                  |
| 7. Canned soybean, bottled soybean                              | Soybean                  |
| 8. Kinako (roasted soybean flour)                               | Soybean                  |
| 9. Roasted Soybean                                              | Soybean                  |
| 10 Item containing food of items 1 to 9 as a main ingredient    | Soybean                  |
| 11 Item containing soybean (for cooking) as a main ingredient   | Soybean                  |
| 12 Item container soybean flour as a main ingredient            | Soybean                  |
| 13 Item containing soybean protein as a main ingredient         | Soybean                  |
| 14 Item containing edamame (green soybean) as a main ingredient | Edamame                  |
| 15 Item containing soybean sprouts as a main ingredient         | Soybean sprouts          |
| 16 Corn snacks                                                  | Corn                     |
| 17 Corn starch                                                  | Corn                     |
| 18 Popcorn                                                      | Corn                     |
| 19 Frozen Corn                                                  | Corn                     |
| 20.Canned or bottled corn                                       | Corn                     |
| 21 Item containing corn flour as a main ingredient              | Corn                     |
| 22 Item container corn grits as a main ingredient               | Corn                     |
| 23 Item containing corn (for processing) as a main ingredient   | Corn                     |
| 24 Item containing food of items 16 to 20 as a main ingredient  | Corn                     |

#### Implementation of Labeling

1. This public notification shall be enforced on the enforcement day of the Law for the partial modification of the Law Concerning Standardization and Proper Labeling of Agricultural and Forest Products (Law No.108 of 1999) and shall apply to the processed foods manufactured, processed or imported, and to the perishable foods sold after April 1, 2001.

2. The list of designated agricultural products in Attached Table 1 and the list of processed foods in Attached Table 2 shall be updated every year taking into

considerations the following;

commercialization of new genetically modified agricultural products; actual situation concerning the distribution and use as raw materials of genetically modified agricultural products; actual situation concerning the removal and dissolution of the recombinant DNA and the resulting protein; new findings about progress in detection methods; and consumers concerns.

3. This public notification shall be reviewed taking into considerations the following, in addition to the items mentioned above 2; the actual situation concerning the treatment of genetically modified agricultural products and processed foods which were made of them at their production, manufacturing, distribution and processing sites of perishable foods and processed foods; and advancements in international standard elaboration.

## Appendix 9

### Promotion of Activities to Build Public Acceptance (PA) of Biotechnology in Japan

#### 1. Background and objectives

Biotechnology in agriculture, forestry, fisheries and food industry has reached at the practical stages. General public, however, are not familiar with recombinant DNA (rDNA) technology, and some seem to feel uncomfortable with biotechnology. In order to promote agricultural biotechnology, it is important to give precise information about biotechnology, especially rDNA technology, to general public so that they can comfortably accept biotechnology and the products.

Ministry of Agriculture, Forestry and Fisheries (MAFF) promotes activities to build perception of general public about rDNA technology and the safety of the products.

#### 2. Outline

##### (1) Support to PA activities of Biotechnology

###### (Lecture and Practice on Biotechnology)

Lectures and practical experiments on Biotechnology for train key-persons who support PA activities of biotechnology in each areas.

(1995-96)

Two times of five days-seminar were held in Tsukuba on July-August under supporting MAFF Institutes. Forty peoples (95) and fifty peoples (96) including dieticians, high school teachers, prefecture officers and researcher of private-sector participated.

(1997)

Two times of five days-seminar were held in Tsukuba on July-August under supporting MAFF Institutes. Fifty peoples including dieticians, high school teachers, prefecture officers and researcher of private-sector participated.

(1998-99)

One times of three days-seminar were held in Tsukuba on July under supporting MAFF Institutes. Forty peoples including dieticians, high school students.

Two times of four days-seminar were held in Tsukuba on July-August under supporting MAFF Institutes. Eighty peoples including dieticians, high school teachers, prefecture officers and researcher of private-sector participated.

##### (2) Local PA activities of Biotechnology

(Practical Class on Biotechnology and Seminars)

1) Lectures and practice

Lectures and practical experiments of rDNA techniques for consumers, high school teachers and farmers in local cities.

(1995)

Two seminars were held in Hiroshima and Kumamoto Prefecture on August under supporting MAFF Local Research Experimental Station. 120 and 80 peoples each including staffs of agriculture-coop, high school teachers, prefecture officers and students of universities participated.

(1996)

Two tree days seminar were held in Sapporo and Akita on August under supporting MAFF Local Research Experimental Station. 120 and 80 peoples each including staffs of agriculture-coop, high school teachers, prefecture officers and students of universities participated.

(1997)

Two tree days seminar were held in Zentsuji/Okayama and Jouetsu/Kanazawa on August under supporting MAFF Local Research Experimental Station. 300 and 150 peoples each including staffs of agriculture-coop, high school teachers, prefecture officers and students of universities participated.

(1998)

One two days seminar(only lectures and practical experiments) were held in Nishigoushi/Kumamoto on August under supporting MAFF(Kyusyu Research Experimental Station). 10 peoples each including high school teachers. Seminar (only lectures and practical experiments) was held in An-nou/Mie on August under supporting MAFF( National Research Institute of Vegetable, Ornamental Plants and Tea). 10 peoples each including high school teachers.

(1999)

One two days seminar were held in Kitakami/Iwate on September under supporting Prefectural Research Experimental Station. 111 peoples each including staffs of agriculture-coop, high school teachers, prefecture officers and students of universities participated. One two days seminar were held in Sapporo/Hokkaido on August under supporting Hokkaido Research Experimental Station. 201 peoples each including staffs of agriculture-coop, high school teachers, prefecture officers and students of universities participated.

2) Symposium

Symposium is held named as "Biotech-forum in Living ", in cooperation with universities, local biotechnology organizations and private-sectors.

(1995)

The "Biotech-forum for Living in Nagoya" was held at Nagoya on November, 1995. The audiences of the Symposium was about three hundreds peoples and 6,800 peoples visited the exhibition held as an annex during 3days. In the exhibition, transgenic petunia, fusant between cabbage and Chinese cabbage using embryo rescue technique and other food products through biotechnology were shown.

(1996)

The "Biotech-forum for Living in Kyoto" was held at Kyoto on October, 1996 and 350 peoples were attending in the Symposium. An exhibition of Biotechnology was held at Izumi-Sano city during 2days.

(1997)

The "Biotech-forum for Living in Tokyo" was held at Tokyo on October, 1997. The audiences of the Symposium was about 150 peoples and many peoples visited the exhibition held as an annex during 3days on November, 1997. In the exhibition, transgenic rice and carnation, fusant between cabbage and Chinese cabbage using embryo rescue technique and other food products through biotechnology were shown.

(1998)

The "Biotech-forum for Living in Fukuoka" was held at Fukuoka on November, 1998. The audiences of the Symposium was about 85 peoples and many peoples visited the exhibition held as an annex during 3days on November, 1998. In the exhibition, transgenic rice and carnation, fusant between cabbage and Chinese cabbage using embryo rescue technique and other food products through biotechnology were shown.

(1999)

The "Biotech-forum for Living in Tokyo" was held at Tokyo on November, 1999. The audiences of the Symposium was about 530 peoples and many peoples visited the exhibition held as an annex during 3days on November, 1999. In the exhibition, transgenic rice and carnation, pumpkin using embryo rescue technique and other food products through biotechnology were shown. The exhibition of the real thing of the agricultural product, livestock and also food where it was developed by Biotechnology. Sampling experience of the clone beef

### 3. Organization in charge

Society of Techno-Innovation for Agriculture, Forestry and Fisheries  
(STAFF)

## Appendix 10

### CURRENT STATUS OF R&D IN BIOTECHNOLOGY AND ITS PRACTICAL APPLICATION IN AGRICULTURE, FORESTRY, FISHERIES AND THE FOOD INDUSTRY IN JAPAN

February, 2000

#### 1. Agriculture and Forestry

##### (1) Cell and tissue cultures

The cell and tissue culture techniques are already used practically for the propagation of crop seedlings and for plant breeding.

The embryo culture and anther culture techniques as well as mutants appearing in a cell culture are used for plant breeding. These methods are used in particular for the breeding of new varieties of rice, vegetables and fruit trees. Seventy percents of strawberry seedlings are now produced virus-free and some 150 facilities have been established for this purpose.

##### (2) Cell fusion

Oretachi a new cross between orange (*Citrus Sinensis*) and karatachi (*Citrus trifoliata*), has been experimentally developed by using the cell fusion technique in Japan. Varieties of tobacco and hiratake (an edible mushroom) improved through cell fusion are actually cultivated.

##### (3) Recombinant DNA (Transgenic plant)

The Recombinant DNA (rDNA) technique is expected to bring about a great progress in the improvement of breeding technology and the development of new plant varieties showing high quality and high yield, such as those with excellent pest and disease resistances, those with environmental stress tolerance, etc.

In the USA, a late ripening tomato variety (FLAVR SAVRTM) developed through the rDNA technology was commercialized as the world's first recombinant food in May, 1994. More than 9,000 field trials of transgenic plants had been already tested in the world by 1996.

In Japan, more than 40 transgenic plants have been already developed. A tomato variety resistant to tobacco mosaic virus (TMV) has been cultivated in ordinary testing field since 1992. Two rice varieties resistant to rice stripe virus (RSV) and a petunia variety resistant to cucumber mosaic virus (CMV) have also been cultivated in ordinary field since 1994. Other virus-resistant melon, tobacco, potato varieties as well as a low protein rice variety and a low allergen rice variety, two late ripening tomato varieties, a long-life carnation variety, three herbicide-tolerant canola varieties, and other herbicide-tolerant soybean and maize varieties have been tested in confined fields for the assessment of

their effects on the environment.

## 2. Livestock

### (1) Embryo transfer

The application of the embryo transfer (ET) technique to the cow has progressed in Japan. The number of calves born through ET is increasing and some 15,000 calves were born in 1997.

Research on in vitro fertilization and nuclear transplantation is also carried out. Some 2,100 calves were born through in vitro fertilization in 1997, and successful experiments for producing clone calves through nuclear transplantation were reported in 1997.

### (2) Transgenic animal

A gene engineering process has been established for small experimental animals such as mouse. In Japan, many animal lines with different genetic characteristics have been developed and are used in laboratories with a view to developing new pharmaceutical. The introduction of a gene to a fertilized chicken egg through micro-injection was successfully carried out for the first time in the world in 1992 by Japanese national institutes, and the production of chimera pigs were successfully carried out in 1994 by the National Institute of Animal Industry.

Overseas private firms and universities have successfully developed transgenic animals for the production of physiologically active substances by utilizing their mammary glands.

### (3) Animal health

A live vaccine of swine Aujeszky disease virus developed by means of gene engineering and a cat interferon produced in silkworm are practically applied in Japan and the R&D in rDNA vaccine against cattle leukemia is underway.

## 3. Fisheries

Triploids and female fish populations are now used to increase the productivity of some fish species (e.g. rainbow trout, flat fish). The Fisheries Agency drew up the Guidelines for the Utilization of Triploid Fish, and others in 1992 for the appropriate application of this technology in aquaculture. The guidelines enumerated characteristics which should be tested before the practical application of such fish, and eleven lines had been tested by 1996.

## 4. Food industry

The cell fusion technique has been applied for the development of new koji (rice mold)

and other yeasts for the production of shochu (Japanese spirit), sake and bread. High fructose syrup, cyclo-dextrin (CD) and erythritol have been produced in a bioreactor containing fixed enzymes and microorganisms. rDNA microorganisms have been used for the production of chymosin, an enzyme used for cheese production in Europe and North America. A cheese made from rDNA chymosin is imported in Japan.

#### 5. Promotion policy of the Ministry of Agriculture, Forestry and Fisheries in the field of biotechnology

##### (1) Promotion of R & D

Biotechnology is a key technology to solve the global food, environment and energy issues, and in particular to improve the productivity and quality of agriculture, forestry, fisheries and the food industry. However, there are a number of issues that must be confronted before the full-scale application of advanced technologies, such as the rDNA technology, can be achieved. Therefore, the Ministry of Agriculture, Forestry and Fisheries (MAFF) is promoting advanced and basic R & D in its research facilities, such as the National Institute of Agrobiological Resources (NIAR). MAFF is also providing research fund to universities and supporting private companies and prefectures.

Specifically, MAFF is conducting the following research projects :

Analytic research on rice genome;

Development of recombinant DNA technology for the future generation;

Integrated research program for the use of biotechnological procedures for plant breeding;

Development of efficient methods for the animal genome analysis and for the utilization of important genes;

Development of highly functional materials through the structural modification of carbohydrates;

Basic research on safety assessment for practical application of recombinant DNA organisms;

DNA bank and Gene bank;

MAFF is supporting R & D projects in the private sector through the Research Association for Mining and Manufacturing Technology and the Society for Techno-Innovation of Agriculture, Forestry and Fisheries (STAFF). Its support program also includes the investment and loan to the private sector through the Bio-oriented Technology Research Advancement Institution (BRAIN) as well as financial aids from

the Japan Development Bank, etc. and various tax measures favoring biotechnology projects of the private sector.

For the promotion of biotechnology in regional areas, MAFF is subsidizing prefectures for the promotion of biotechnology R&D and the improvement of their facilities for application of biotechnology such as tissue culture and embryo transfer. Permanent secretariats have been established in six districts to promote the application of biotechnology in cooperation with industries, universities and local governments.

## (2) Setting up of guidelines for rDNA

It is generally recognized that any unique hazard has not been identified with respect to the rDNA technique until now. However, it is necessary to take into account potential effects on the human body and environment.

Therefore, the OECD Council published a recommendation concerning safety considerations for applications of recombinant DNA organisms in industry, agriculture and the environment" in 1986. MAFF issued, in 1989, "Guidelines for the Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and other Related Industries" on the basis of the OECD recommendation in order to promote an appropriate application of rDNA organisms while ensuring their safety.

At the time of application of a rDNA organism, any person can ask MAFF to examine whether its safety evaluation is in conformity with the guidelines.

Ninety entries have been approved by MAFF, including 48 transgenic plants.

Eighteen rDNA microorganisms producing specific amino acids, enzymes and pharmaceutical products as well as 24 transgenic small experimental animals.

The Ministry of Health and Welfare notified the guidelines including the food safety assessment of crop plants derived through biotechnology in February 1996. Furthermore, MAFF also notified the guidelines of the safety assessments for animal feed and feed additive derived through biotechnology in April 1996. Seven transgenic crops including herbicide tolerant-canola and -soybean, and insect resistant -potato and -corns have complied with the MHW Guidelines by the Minister at September 1996, after being reviewed by the Food Sanitation Investigation Council. Furthermore, the six transgenic crops without insect resistant potato from above have also complied with the MAFF-feed guidelines by the Minister at September 1996.

Eight transgenic crops including herbicide tolerant-canola and -corn, and insect resistant potato, corns and -cotton have complied with the MHW Guidelines by the Minister at May 1997, after being reviewed by the Food Sanitation Investigation Council. Furthermore, the six transgenic crops without insect resistant potato and herbicide tolerant-canola from above have also complied with the MAFF-feed guidelines by the Minister at June and March 1997.

Five transgenic crops including herbicide tolerant-canola and -cotton, and ripening

delayed tomato have complied with the MHW Guidelines by the Minister at December 1997, after being reviewed by the Food Sanitation Investigation Council.

Two transgenic crops including herbicide tolerant-canola have complied with the MHW Guidelines by the Minister at December 1998, after being reviewed by the Food Sanitation Investigation Council.

Seven transgenic crops including herbicide tolerant-canola, corn and – sugar beet, and herbicide tolerant / insect resistant -cotton have complied with the MHW Guidelines by the Minister at November 1999, after being reviewed by the Food Sanitation Investigation Council.

### (3) Enhancement of Public Acceptance

To build perception of general public about rDNA technology and its safety (public acceptance (=PA)) is an important factor underlying the practical application of the technology. Therefore, the following measures are required:

To provide the public with appropriate information:

To make available information on the rDNA techniques as such and the results of research and development in biotechnology, the administrative framework for ensuring safety and safety assessment data.

Enhancement of PA by showing examples of food derived through the rDNA technology:

To provide more opportunities for local residents and consumers to see and touch the final products derived from the rDNA technology:

To increase the public awareness of the merit of rDNA products.

PA from a long-term viewpoint:

To enhance PA of biotechnology among younger generations;

To convince the general public of the fact that biotechnology is indispensable for solving the global food and environmental issues.

To enhance PA in the private sector, as well as universities and local governments.

To take necessary measures for the appropriate implementation of the provisions of the guidelines for the rDNA application.

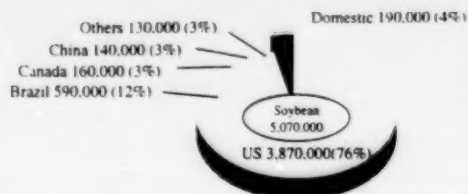
# Appendix 11

## Comparison on Labeling Regulations

| Classification of GMO foods                                                                                                                                     | Canada & U.S.                                               | EU                                                                                                                                           | Japan                                                                                                                                                                                                                                                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1) GMO products and processed foods derived therefrom which are NOT equivalent to conventional foods in composition, nutrient and intended use.                 | Mandatory labeling on compositions which are not equivalent | Mandatory labeling (no example indicated yet)                                                                                                | Mandatory labeling (Example indicated as "Soybean, high oleic acid, genetically modified")                                                                                                                                                                                                             |
| 2) Substantially equivalent to conventional foods with r-DNA or protein produced thereby persists/exists after the manufacturing process.                       | NOT required (Voluntary labeling permitted)                 | Mandatory Labeling when DNA and protein exist<br><br>Labeling not required when DNA and protein do not exist. (Voluntary labeling permitted) | Mandatory labeling when GMO ag. products were used as main ingredients.<br><br>Mandatory labeling to say "non-segregated" when GMO ag. products used were not segregated<br><br>Voluntary labeling or no labeling required when non-GMO ingredients used were segregated (with proofs of IP handling). |
| 3) Substantially equivalent to conventional foods with r-DNA and protein produced do not exist as result of removal/decomposition during manufacturing process. | NOT required (Voluntary labeling permitted)                 | Not required (Voluntary permitted)                                                                                                           | Not required. (Voluntary permitted)                                                                                                                                                                                                                                                                    |

### Appendix 3. Japanese Import of Major Commodities affected by GMO

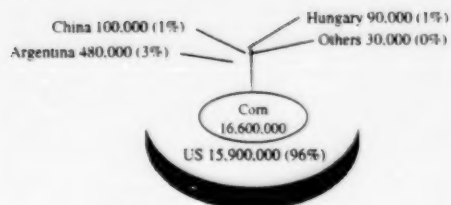
#### Soybean



Estimated % of GM acreage in U.S.  
 ---- 50% (1999)



#### Corn



Estimated % of GM acreage in U.S.  
 ---- 33% (1999)



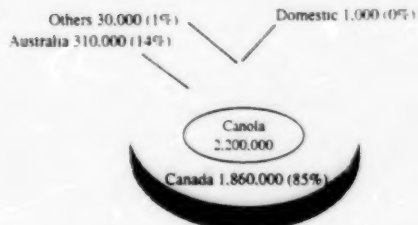
#### Potato



Estimated % of GM acreage  
 in U.S.---- 3% (1999)

No fresh potato is imported. 700,000 tons of processed products (frozen, powdered, mashed, fried) are imported. (1997)

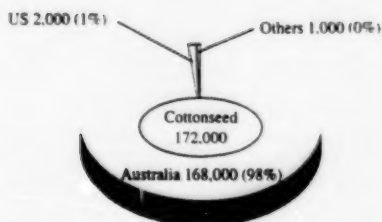
#### Rapeseed & Canola



Estimated % of GM acreage  
 in Canada--- 55% (1999)



#### Cottonseed



Estimated % of GM acreage  
 in U.S. ---- 66% (1999)

# Appendix 12 : GMO Chronology of Events

|           | Japan                                                                  |                                                            |                                 | World                                                              |
|-----------|------------------------------------------------------------------------|------------------------------------------------------------|---------------------------------|--------------------------------------------------------------------|
|           | government                                                             | consumer                                                   | industry                        |                                                                    |
| 1953      |                                                                        |                                                            |                                 | DNA double helix structure discovered by Watson and Crick, USA/UK. |
| 1976      |                                                                        |                                                            |                                 | NIH, US, establishes guidelines for DNA testing                    |
| 1986      | MAFF issues guidelines for application                                 |                                                            |                                 | OECD council publishes recommendation on safety.                   |
| 1989      |                                                                        |                                                            |                                 | Triptophane incident (1988-89)                                     |
| 1991      | MHW starts assessment of safety basis OECD Guidelines                  |                                                            |                                 |                                                                    |
| 1996 Feb. | MHW issues Guidelines for Safety                                       |                                                            |                                 | Birth of Dolly the sheep, UK.                                      |
| April     | MHW issues Guidelines for animal feed and feed additives               |                                                            |                                 | Superweed (Holland), Nature Report                                 |
| Aug.      | MHW, Food Safety Investigation Council assess safety of 7 crops (8/26) |                                                            |                                 |                                                                    |
| Nov.      |                                                                        | Import of GM soybean starts<br>CUJ starts non-GMO Campaign | Japan starts importing GM foods |                                                                    |
| 1997 May  | MAFF establishes GMO Committee Among Food Labeling Council             |                                                            |                                 | CODEX begins labeling standards discussion                         |
| July      | MHW, 22 crops safety assessed                                          | Non-GMO Campaign grows (1 million signature)               |                                 |                                                                    |

# Appendix 12 : GMO Chronology of Events

|            | Japan                                                                                                      |                                                                                                                                                    |                                     | World                                     |
|------------|------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------------|
|            | government                                                                                                 | consumer                                                                                                                                           | industry                            |                                           |
| Dec.       |                                                                                                            | "Fear of GMO foods" published (12/1)                                                                                                               |                                     |                                           |
| 1998 Aug.  | Lower House subcommittee on consumer affair favours labeling<br>MAFF pamphlet : "Our Life & Biotechnology" | Fujisawa, Zama cities school lunch switch to non GMO<br>MAFF consumer poll on labeling<br>My Tofu project begins.                                  |                                     | Jan/August Dr. Pusztai Incident           |
| Dec.       | MAFF reversal on labeling, basis US complaint                                                              | Bug's video made (JDF)                                                                                                                             |                                     |                                           |
| 1999 March |                                                                                                            | Cloned beef on market                                                                                                                              |                                     | rBGH prohibited in Canada                 |
| April      |                                                                                                            |                                                                                                                                                    |                                     |                                           |
| May        |                                                                                                            |                                                                                                                                                    |                                     | Nature report on Monarch Butterfly (5/20) |
| mid        |                                                                                                            | World Action Day. CUJ presents 1.7 million signatures (5/31)<br>Non-GMO Campaign takes off<br>More on labeling debate<br>CUJ Kirm boycott campaign |                                     |                                           |
| July       |                                                                                                            | 27 organization submit request to MAFF                                                                                                             | Mitsubishi/Takara inspection (7/31) |                                           |
|            |                                                                                                            | CUJ corn snacks complaint (7/29)                                                                                                                   |                                     |                                           |

# Appendix 12 : GMO Chronology of Events

|       | Japan                                                             |                                                                                         |                                                                                                                                                                                                                                          | World                                          |
|-------|-------------------------------------------------------------------|-----------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
|       | government                                                        | consumer                                                                                | industry                                                                                                                                                                                                                                 |                                                |
| Aug.  | MAFF committee final report suggests labeling requirement (8/4)   |                                                                                         | Kirin freeze "Flavor Saver" & declare not to use GM corn. Sapporo Breweries join Kirin. (8/24)<br><br>Fuji Oil to stop using GM soya (8/31)<br><br>Tohato snack switch to French corn grits. (8/31)<br><br>Asahi Breweries announcement. |                                                |
| Sept. | MHW Safety assessment reaches 29 crop plants & 6 additives (9/10) | Cloned beef sales (2nd)                                                                 | JUSCO starts labeling (9/9)<br><br>Nisshin Food stop using GM Soya (9/10)<br><br>non-GMO insurance announced (9/21)<br><br>Honda - to build plant in US to secure non-GM soybean                                                         | Gallop Polls                                   |
| Oct.  | Patent office guideline                                           | CUJ issues letters to US farmers (10/6)                                                 | Breweries switch to non-GM corn                                                                                                                                                                                                          | EU follows with labeling requirement           |
| Nov.  | MAFF survey on labeling                                           | Tokyo Met. Gov't poll<br><br>Kawagoe school lunch switch<br><br>MAFF/Finance Corp. poll | Baby food industry's switch announcement<br><br>Tofu, bean paste, soyamilk & corn snack industries join                                                                                                                                  | October 19 -World population reaches 6 billion |

| Japan     |                                                                            |                                                   |                                                                              | World                                             |
|-----------|----------------------------------------------------------------------------|---------------------------------------------------|------------------------------------------------------------------------------|---------------------------------------------------|
|           | government                                                                 | consumer                                          | industry                                                                     |                                                   |
|           | MAFF labeling requirement announced through JAS standard revision (1/1/29) | JCCU statement for OECD<br>My Tofu project grows. | Nikkei Survey of food manufacturers (11/1)                                   | Angus Reid Poll                                   |
| 2000 Feb. | MAFF committee on Environment                                              | JCCU opinion submitted to MAFF                    | "Pigeon Knows" commercial on TV<br>Nippon Flour Mills switch to non-GM corn. |                                                   |
| March     | MAFF pamphlet :<br>"Your Life & GMOs"                                      |                                                   |                                                                              |                                                   |
| May       | MHW announcement on mandatory safety assessment (5/1)                      |                                                   | Tokyo Grain Exch starts non-GMO bean futures                                 | Clinton Initiatives of Food & Biotechnology (5/3) |
| June      |                                                                            |                                                   | Suntory - Moondust<br>Japan Tabacco - new rice<br>JAFF research - new rice   |                                                   |
| 2001 Apr. | New Labeling to start (4/1)                                                |                                                   |                                                                              |                                                   |
| May       |                                                                            |                                                   |                                                                              |                                                   |

## Appendix 13

### **Press Reports Announcing Corporations Switch to Non-GMO**

#### **1. Corn**

a) As result of CUJ claims of Bt corn slipping into corn snacks in July of 1999, **Tohato Inc.**, another user of Bt corn and a leading corn snack manufacturer who was dependent on U.S. corn, decided to switch to corn grits made in France in order to avoid the GM label." [Reuters, August 31, 2000].

b) Nippon Flour Mills, Japan's second largest flour millers, has switched to non-GM corn in its production of corn grits. They are also considering switching cornstarch with wheat starch. [Nikkei Shinbun, December 20, 1999]

c) Bourbon Corporation, one of Japan's leading snack manufactures with 850 million in 1999 sales announced on June 12, 2000 that it will stop using corn sweeteners and will move to cane sugar and potato-based sweeteners for its biscuits and confection products.

The company did not reveal how much the switch will cost; but says that it will not pass any costs on to consumers. [www.Cropchoice.com]

#### **2. Soybean**

a) **Kurehara Food Products** of Toyama has shifted its procurement of soybeans from the US to Canada even though Canadian beans cost 20% more. However, fearing that GMOs may turn up among Canadian soybeans, too, the company is procuring Chinese and domestic Japanese soybeans in addition to the Canadian source. It is considering procurement from Australia as well. [Hokkoku Shinbun]

b) **Japan Tofu Association's** Hironori Kijima, director general, expects GM labeling will have the industry switch totally to non-GM soybeans. "We want to avoid the GM label as it could hurt the image of our products...We will be asked to pay high premiums for non-GM but we have no other option." [Reuters, August 23, 1999]

c) **Kibun Food Chemifa Co. Ltd**, Japan's largest soybean milk maker, will stop using GM ingredients by March 2000. The company plans to use rice bran oil as a substitute for corn oil and replace high fructose corn syrup with sugar. Officials said, "we have decided to eliminate all the GM ingredients from soymilk products, which have marked double-digit growth for the past several years due to its image as a healthy drink."

Kibun accounts for about a 50 percent share in Japan's soymilk market worth some 17 billion yen in 1999. [*Reuters*, Dec. 21, 1999]

d) **Nisshin Food Products** noted September 10, 1999 that it intended to stop using GM soybeans. In doing so, it joined Kirin but had the distinction of being the first instant noodle maker to do so.

[*Comline* 10/09/99]

e) **Japanese farmers** who do not use genetically modified seeds, are enjoying a huge demand for their beans – even at three to four times the price of imported ones.

[*Washington Post*, January 24, 2000]

f) **Marubeni's** order of 700,000 tons -- is all non-GMO, and will cost 15 percent more. Two years ago, only half the order was for GMO-free beans.

[*Washington Post*, January 24, 2000]

### 3. Food Processors in Dilemma

"Faced with consumer backlash, some food manufacturers have started eliminating GM ingredients from their products. Japan's beer industry has decided to stop using starch and grits produced from GM corn to make beer by 2001. Baby food makers also plan to eliminate basically all the GM ingredients from their products by April 2001. Companies which have announced plans not to use GM ingredients include makers of 'tofu' soybean curd, soybean paste, soybean milk, soy protein food and corn snacks."

"Other companies are cautious about switching due to uncertainty about whether consumers will pay extra in case it was necessary to pass on the increased cost. Bulk users of GM crops such as oilseed crushers, corn syrup makers and feed producers are

reluctant to ship because they consider it unrealistic due to the mass volume required.”

[*Netlink 28/10/99*]

**4. Kume Quality Products**, a maker of the popular fermented soybean dish “Natto,” ran a TV commercial in late 1999 showing a pigeon confronted with two soybeans: Which to choose? It makes a quick meal of one bean – the one right from Mother Nature, according to the voice-over. Not all beans are alike, the voice tells viewers. Some, it warns, according to the story, are GMO.

The government announcement on mandatory labeling of GMO has given makers of undoctored foods an obvious marketing opportunity. The company spokesman was quoted as saying, “Consumers are becoming increasingly uneasy with GMOs, so we just wanted to let them know our products are natural.”

[*Dow Jones*]

Appendix 14

Japanese Consumption of Edible Soybean - Volume by Use

unit: 1,000T

| year               | total | Miso paste | Soy sauce | Tofu & its product | Natto | Koya tofu | Soya milk | Others |
|--------------------|-------|------------|-----------|--------------------|-------|-----------|-----------|--------|
| 1988               | 992   | 179        | 6         | 485                | 99    | 31        | 4         | 188    |
| 1989               | 1010  | 177        | 11        | 490                | 104   | 31        | 4         | 193    |
| 1990               | 994   | 172        | 24        | 494                | 107   | 31        | 3         | 163    |
| 1991               | 1013  | 171        | 22        | 494                | 108   | 31        | 3         | 184    |
| 1992               | 1037  | 176        | 25        | 494                | 108   | 31        | 3         | 200    |
| 1993               | 965   | 173        | 23        | 492                | 109   | 31        | 3         | 134    |
| 1994               | 978   | 165        | 22        | 493                | 109   | 30        | 3         | 156    |
| 1995               | 974   | 162        | 27        | 493                | 110   | 30        | 3         | 149    |
| 1996               | 1038  | 167        | 27        | 492                | 115   | 30        | 3         | 204    |
| 1997               | 1019  | 165        | 26        | 494                | 122   | 30        | 3         | 179    |
| 1998               | 1046  | 162        | 26        | 495                | 128   | 30        | 4         | 201    |
| 1999               | 1017  | 162        | 30        | 492                | 127   | 29        | 6         | 171    |
| 2000<br>(estimate) | 1020  | 162        | 31        | 493                | 129   | 29        | 7         | 169    |

Source : MAFF

## Appendix 15

### **GMO Testing Methods Currently in Use in Japan**

Takara Shuzo Corporation announced that it would open a recombinant DNA food-testing service. Since April 1998, the company has tested 120 food samples and has found that 10% contained some amount of recombinant DNA. These checks are not legally mandated, but many producers are having their products tested in response to the growing consumer concerns over genetically altered foods.

[*The Food Biotechnology Market in Japan*, The Team Canada Market Research Centre]

The Oilstuff Inspectors Corp., a government company operated by the Agriculture and Transport ministries started testing soybean, corn and other grain imports for genetically modified (GMO) content from November 1999. Oilstuff Corp. began certifying imports for Marubeni, Itochu, Sumitomo, Mitsui and other major trading houses, so they can pass their commodities along to the food manufacturers who want to apply "GMO-free" labels on their products. The company uses the ELISA (enzyme-linked immunosorbent assay) test method, said to be capable of measuring GMO content to within 0.1%. The trading houses pay about Yen 20,000 per sample for the tests.

[*Nikkei Shinbun*, August 1999]

SRL Inc, Japan's largest clinical laboratory, sees a big opportunity in the food testing business as food processors are eager to prove their products don't contain GMOs. SRL has more than 10 years experience in genetic testing in the clinical field. The company has started testing using the polymerase chain reaction (PCR) method, a qualitative testing of DNA. SRL plans to start quantitative testing of proteins resulting from gene alteration, using the ELISA method.

The ELISA method is applicable to testing of raw materials, while the PCR method can be applied to the testing of both raw materials and processed foods.

SRL charges Yen 30,000 for the testing of one food product and slightly less for raw materials testing.

[*Reuters*, October 14, 1999]

Dr, Stuart Boag of the Australian Government Analytical Laboratories (AGAL) was quoted in *Reuters* (October 20, 1999) exclaiming "someone even asked us to test canola which is quite inane because there is no DNA in canola oil anyway... You will be amazed. We go everywhere from bread to tortilla chips to baby food to breakfast cereals and potatoes... Some companies are cashing in on paranoia in some countries saying, could you guarantee our stuff to be GM free?"